PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Loncastuximab tesirine-lpyl (e.g., Zynlonta)	2022010	Continuation criteria added for label and off-label criteria added. **CONTINUATION OF THERAPY:** 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.	Yes	June 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022010
Cabazitaxel (e.g., Jevtana)	2021013	Continuation criteria added for FDA label and off-label indications. **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Documentation indicating disease response to treatment, by stabilization of disease and decrease in size of tumor or tumor spread.	Yes	June 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021013
Talquetamab-tgvs (e.g., Talvey)	2024007	Continuation criteria for FDA label indications updated. Off-label initial and continuation criteria added for multiple myeloma. **FDA-labeled indications** **CONTINUATION OF THERAPY :** 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual has not experienced disease progression during talquetamab-tgvs treatment (Talvey, 2023); **AND** 3. Individual will be using talquetamab-tgvs as a single agent (Talvey, 2023); **AND** 4. Individual has an ECOG performance status of 0-2 (Chari, 2022). **Off-Label Indications**	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024007

		INITIAL APPROVAL: **1. Multiple Myeloma** a. Individual is using as bridge to BCMA CAR-T therapy in relapse and/or refractory myeloma (NCCN 2A); **OR** b. Individual is using as therapy for previously treated multiple myeloma for relapsed/refractory disease in the following circumstances: i. as a single agent in those who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (NCCN 2A); **OR** ii. in combination with teclistamab-cqyv 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 talquetamab-tgvs treatment (Talvey, 2023); **AND** 3. Individual has an ECOG performance status of 0-2 (Chari, 2022).			
Siltuximab (e.g., Sylvant)	2021014	FDA label and off-label continuation criteria added. Off-label coverage criteria updated. **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Documentation indicating disease response to treatment by stabilization of disease.	Yes	June 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021014

		<u>Off Label Indications</u> 1. Management of **Immunotherapy-Related Toxicities-CAR T-Cell-Related Toxicities**: a. Management of G4 cytokine release syndrome that is refractory to high-dose corticosteroids and anti-IL-6 therapy (NCCN 2A); **OR** b. Replacement for second dose of tocilizumab when supplies are limited or unavailable for management of (NCCN 2A): i. G1-4 cytokine release syndrome (CRS); **OR** 1. G1-4 neurotoxicity as additional therapy if concurrent CRS; **OR** c. As alternative cytokine blockade in addition to tocilizumab (NCCN 2A): i. G2 Cytokine Release Syndrome (CRS) if symptoms persist for more than 24 hours; **OR** ii. G3-4 CRS if symptoms persist despite combination therapy with tocilizumab and corticosteroids for G3-4 CRS; **OR** 2. **Kaposi Sarcoma-KSHV-Associated Inflammatory Cytokine Syndrome**: a. Addition to current Kaposi Sarcoma (KS)-directed systemic therapy for refractory/progressive Kaposi-sarcoma associated herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS) (NCCN 2A); **OR** 3. **Castleman Disease**: a. First-line therapy as a single agent (NCCN 2A): i. For surgically unresectable/or if incomplete resection of unicentric Castleman disease (UCD) with primarily inflammatory			

		symptoms that is human Immunodeficiency virus (HIV)-1-negative; **OR** ii. As alternate first-line therapy for UCD that is human herpesvirus 8 (JJV8)-negative/human Immunodeficiency virus (HIV)-1-negative if disease remains surgically unresectable after first-line therapy or if incomplete resection; OR iii. For multicentric CD (MCD) with criteria for active disease present with no organ failure that is HHV8-negative/HIV-1-negative (nonsevere); **OR** iv. As alternate first-line therapy for MCD with criteria for active disease present with no organ failure [hat is HHV8-negative/HIV-1 negative (nonsevere)]; **OR** v. For MCD (fulminant/severe) with or without organ failure that is HHV8-negative; **OR** b. Second-line and subsequent therapy as a single agent for relapsed/refractory or progressive unresectable unicentric CD for disease that is HIV 1-negative and HHV 8-negative (NCCN 2A): i. Surgically unresectable/or if incomplete resection of unicentric Castleman disease (UCD) that is human Immunodeficiency virus (HIV)-1-negative/human herpesvirus 8 (HHV8)-negative; **OR** ii. Multicentric CD in individuals with criteria for			

		active disease present with no organ failure that is HHV-8 negative; **OR** iii. Fulminant/severe disease with or without organ failure that is HHV8-negattive; **AND** 4. Will not be used for any of the following conditions: a. Direct treatment of multiple myeloma; **OR** b. Myelodysplasia syndrome; **OR** c. Other solid tumors.			
Polatuzumab Vedotin-piiq (e.g., Polivy)	2021020	Off-label coverage criteria updated for B-Cell lymphomas. 1. **B-Cell Lymphomas**: a. Mantle Cell Lymphoma (NCCN 2A); **OR** b. Diffuse Large B-Cell Lymphoma (NCCN 1 and 2A); **OR** c. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma (NCCN 1 and 2A); **OR** d. High-Grade B-Cell Lymphomas (NCCN 2A); **OR** e. Burkitt Lymphoma (NCCN 2A); **OR** f. HIV-Related B-Cell Lymphomas (NCCN 2A; **OR** g. Post-Transplant Lymphoproliferative Disorders (NCCN 2A).	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021020
Margetuximab-cmkb (e.g., Margenza)	2021025	Continuation criterion regarding unacceptable toxicity moved to policy guidelines. **CONTINUATION OF THERAPY:** 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.	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021025

Obinutuzumab (e.g., Gazyva)	2021019	FDA label coverage criteria updated to include new indication for active lupus nephritis. Off-label indications updated for B-Cell lymphomas updated. **<u>FDA Labeled Indications</u>** **The use of this drug is covered if an FDA-approved oncologic indication exists [not listed as an indication below with the member meeting all of the additional requirements of the prescribing information (package insert listed in the "Indications and Usage").** **INITIAL APPROVAL:** 1. Individual is 18 years of age or older (Gazyva, 2021); **AND** 2. Individual is free from active infection (Gazyva, 2021); **AND** 3. Individual has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered during treatment(Gazyva, 2021); **AND** 4. Individual has been screened for hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy. If the individual has evidence of current or prior HBV infection, they will be monitored for HBV reactivation during treatment(Gazyva, 2021); **AND** 5. Individual has a documented diagnosis of the following: a. Chronic Lymphocytic Leukemia (CLL); **AND** i. Individual has not previously been treated for CLL (Gazyva, 2021); **AND** ii. Obinutuzumab (e.g., Gazyva) will be used in combination with chlorambucil (Gazyva, 2021); **OR** b. Follicular Lymphoma (FL); **AND** i. Individual has FL relapsed after, or refractory to, a	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021019

		rituximab-containing regimen (Gazyva, 2021); **AND** 1. Will be used in combination with bendamustine followed by obinutuzumab (e.g., Gazyva) monotherapy (Gazyva, 2021); **OR** ii. Individual has not previously been treated for stage II bulky, III or IV FL (Gazyva, 2021); **OR** c. Active lupus nephritis and individual is receiving standard therapy (Gazyva, 2025), **AND** 6. For oncology uses, will be used in combination with chemotherapy followed by obinutuzumab (e.g., Gazyva) monotherapy in individuals achieving at least a partial remission (Gazyva, 2025). **<u>Off-label Indications</u>** **The use of this drug for off-label indications not listed below is subject to policy 2000030.** **INITIAL APPROVAL:** **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. **Hairy Cell Leukemia** (NCCN 2A); **OR** 2. **Castleman Disease** (NCCN 2A); **OR** 3. **B-Cell Lymphomas**: a. Classic Follicular Lymphoma (NCCN 2A); **OR**			

		b. Extranodal Marginal Zone Lymphoma of the Stomach (NCCN 2A); **OR** c. Extranodal Marginal Zone Lymphoma of Nongastric Sites (Noncutaneous) (NCCN 2A); **OR** d. Nodal Marginal Zone Lymphoma (NCCN 2A); **OR** e. Splenic Marginal Zone Lymphoma (NCCN 2A); **OR** f. Mantle Cell Lymphoma (NCCN 2A); **OR** g. Diffuse Large B-Cell Lymphoma (NCCN 2A); **OR** h. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma (NCCN 2A); **OR** i. High-Grade B-Cell Lymphomas (NCCN 2A); **OR** j. Burkitt Lymphoma (NCCN 2A); **OR** k. HIV-Related B-Cell Lymphomas (NCCN 2A); **OR** l. Post-Transplant Lymphoproliferative Disorders (NCCN 2A); **OR** m. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (NCCN 2A); **OR** 4. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma** (NCCN 1 and 2A).			
Trabectedin (e.g., Yondelis)	2021022	FDA label and off-label continuation criterion regarding unacceptable toxicity moved to policy guidelines. Off-label criteria for soft tissue sarcoma updated. **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Durable clinical benefit has been demonstrated while receiving trabectedin,	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021022

		with partial or complete response or stable disease; **AND** 3. Left ventricular ejection fraction (LVEF) has not had an absolute decrease of greater than or equal to 15% from baseline or is not below the lower limit of normal (LLN) with an absolute decrease of greater than or equal to (LVEF results must be within the previous 3 months) (Yondelis, 2020). **Off-label Indications:** 1. **Soft Tissue Sarcoma**: a. Extremity/Body Wall, Head/Neck (NCCN 1 and 2A); **OR** b. Retroperitoneal/Intra-Abdominal (NCCN 1 and 2A); **OR** c. Rhabdomyosarcoma (NCCN 2A); **OR** d. Borderline/Malignant Phyllodes Tumor of the Breast (NCCN 2A); **OR** e. Solitary Fibrous Tumor (NCCN 2A); **OR** f. Dedifferentiated Liposarcoma with or without Concurrent Well-Differentiated Liposarcoma (NCCN 2A); **OR** g. Epithelioid hemangioendothelioma (NCCN 2A); **OR** 2. **Uterine Neoplasms**: a. Uterine Sarcoma (NCCN 2A).			
Blinatumomab (e.g., Blincyto)	2016009	Off-label indications updated. 1. **Pediatric Acute Lymphoblastic Leukemia** (NCCN 2A): a. Single-agent (NCCN 2A); **OR** b. Consolidation therapy in specified combinations (NCCN 2A); **OR** c. In combination with imatinib, dasatinib or ruxolitinib (NCCN 2A); **OR** d. Induction therapy in combination with interfant regimens for infant	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2009048

		ALL with KMT2A status rearranged (NCCN 2A); **OR** e. Therapy for relapsed/refractory BCR::ABL1-negative B-ALL, or in combination with dasatinib or imatinib for relapsed/refractory BCR::ABL1-positive B-ALL as a component of COG AALL1331 regimen (NCCN 2A); **OR** 2. **Acute Lymphoblastic Leukemia**: a. Therapy in combination with a TKI for Philadelphia chromosome-positive B-ALL (NCCN 2A); **OR** b. Therapy as a single agent for Philadelphia chromosome-positive B-ALL for relapsed or refractory therapy (NCCN 2A); **OR** c. Therapy as a single agent for Philadelphia chromosome-negative B-ALL during consolidation therapy (NCCN 2A); **OR** d. Consolidation therapy (if minimal/measurable residual disease negative/unavailable) as a single agent during consolidation cycles 1, 2, 6, 8 of ECOG1910 protocol (NCCN 2A); **OR** e. Sequential consolidation therapy (if minimal/measurable residual disease negative/unavailable) as a single agent as a component of dose-adjusted HyperCVAD (NCCN 2A); **OR** f. Therapy as a single agent in sequential or alternating regimens with inotuzumab ozogamicin, mini-hyperCVAD or POPM regimens (NCCN 2A); **OR** g. Maintenance therapy for Philadelphia chromosome-negative B-ALL (AYA without substantial comorbidities and adults) (NCCN 2A); **OR** h. Therapy for Philadelphia chromosome-negative B-ALL during			

		relapsed/refractory therapy (NCCN 1).			
Levoleucovorin Agents (e.g., Khapzory)	2021007	Title updated, removing Fusilev. Continuation criterion regarding unacceptable toxicity moved to policy guidelines. On May 31, 2022, Spectrum Pharmaceuticals discontinued Levoleucovorin (e.g., Fusilev). **CONTINUATION OF THERAPY:** 1. Individual continues to meet initial approval criteria; **AND** 2. Documentation indicating disease response to treatment, by stabilization of disease.	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021007
Leuprolide (e.g., Lupron) for Oncologic Indications	1997128	FDA label and off-label continuation criterion regarding unacceptable toxicity moved to policy guidelines. Off-label indications for uterine neoplasms and breast cancer updated for leuprolide acetate for depot suspension and leuprolide acetate. **CONTINUATION OF THERAPY:** 1. Individual continues to meet initial approval criteria; **AND** 2. Individual experiences benefit from continued leuprolide treatment. **<u>Off-label Indications</u>** 1. Leuprolide Acetate: a. **Head and Neck Cancers**: i. Salivary Gland Tumors (NCCN 2A); **OR** b. **Uterine Neoplasms:** i. Uterine Sarcoma (NCCN 2A); **OR** c. **Prostate Cancer** (NCCN 1 and 2A); **OR** d. **Breast Cancer:** i. Invasive Breast Cancer (NCCN 1 and 2A); **OR**	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=1997128

		ii. Inflammatory Breast Cancer (NCCN 1 and 2A); **OR** 2. Leuprolide Acetate for Depot Suspension: a. **Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer**: i. Epithelial Ovarian cancer/Fallopian Tube Cancer/Primary Peritoneal cancer (NCCN 2A); **OR** ii. Carcinosarcoma (Malignant Mixed Mullerian Tumors) (NCCN 2A); **OR** iii. Clear Cell Carcinoma of the Ovary (NCCN 2A); **OR** iv. Mucinous Neoplasms of the Ovary (NCCN 2A); **OR** v. Grade 1 Endometrioid Carcinoma (NCCN 2A); **OR** vi. Low-Grade Serous Carcinoma (NCCN 2A); **OR** vii. Malignant Sex Cord-Stromal Tumors (NCCN 2A),			
Eribulin mesylate (e.g., Halaven)	2021011	Coverage criteria for off-label indications updated for soft tissue sarcoma. **CONTINUATION OF THERAPY:** 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. **<u>Off-label Indications</u>** 1. **Soft Tissue Sarcoma**: a. Extremity/Body Wall, Head/Neck (NCCN 1 and 2A); **OR** b. Retroperitoneal/Intra-Abdominal (NCCN 1 and 2A); **OR** c. Rhabdomyosarcoma (NCCN 2A); **OR**	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021011

		d. Borderline/Malignant Phyllodes Tumor of the Breast (NCCN 2A); **OR** e. Dedifferentiated Liposarcoma with or without Concurrent Well-Differentiated Liposarcoma (NCCN 2A); **OR** f. Epithelioid hemangioendothelioma (NCCN 2A).			
Datopotamab deruxtecan-dlnk (e.g., Datroway)	2025007	Coverage criteria updated to include new FDA label and off-label indications. Continuation criteria for FDA label and off-label indications added. **<u>FDA-Labeled Indications</u>** **The use of this drug is covered if an FDA-approved oncologic indication exists [not listed as an indication below with the member meeting all of the additional requirements of the prescribing information (package insert listed in the "Indications and Usage").** **INITIAL APPROVAL:** 1. Individual is 18 years of age or older (Datroway, 2025; NCCN 2A); **AND** 2. Individual is receiving for unresectable or metastatic breast cancer following prior endocrine-based therapy and chemotherapy that is (Datroway, 2025; NCCN 2A): a. Hormone receptor (HR)-positive; **AND** b. Human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-); **OR** 3. Individual is receiving for locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib, lazertinib, osimertinib, dacomitinib) and platinum-based chemotherapy (e.g., cisplatin, carboplatin) (Datroway, 2025).	Yes	June 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025007

		CONTINUATION OF THERAPY: 1. Individual continues to meet the initial approval criteria; **AND** 2. Documentation indicating disease response to treatment, by stabilization of disease and decrease in size of tumor or tumor spread. **<u>Off-Label Indications</u>** **The use of this drug for off-label indications not listed below is subject to policy 2000030.** **INITIAL APPROVAL:** **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. **Breast Cancer**: a. Invasive Breast Cancer (NCCN 2A): i. Second- or subsequent-line therapy as a single agent for those who have received prior endocrine-based therapy and chemotherapy for recurrent unresectable (local or regional) or stage IV (M1) hormone receptor positive and human epidermal growth factor receptor 2 (HER2) IHC 0, 1+, or 2+/ISH negative if not a candidate for fam-trastuzumab deruxtecan-nxki; **OR** ii. Single-agent therapy for recurrent unresectable (local or regional) or stage IV (M1) triple negative			

		breast cancer (TNBC) as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 pathogenic variant; **OR** b. Inflammatory Breast Cancer (NCCN 2A): i. Second- or subsequent-line therapy as a single agent for those who have received prior endocrine-based therapy and chemotherapy for recurrent unresectable (local or regional) or stage IV (M1) hormone receptor positive and human epidermal growth factor receptor 2 (HER2) IHC 0, 1+, or 2+/ISH negative if not a candidate for fam-trastuzumab deruxtecan-nxki; **OR** ii. Single-agent therapy for recurrent unresectable (local or regional) or stage IV (M1) triple negative breast cancer (TNBC) as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 pathogenic variant; **OR** 2. **Non-Small Cell Lung Cancer** (NCCN 2A): a. Subsequent systemic therapy as a single agent for recurrent, advanced, or metastatic disease in those with performance status 0-2, EGFR mutations including: exon 19 del/L858R mutation, S768I, L861Q, G719X or exon 20 insertion, and nonsquamous cell histology (preferred for subsequent therapy; other recommended option for subsequent progression). **CONTINUATION OF THERAPY:**			

		1. Individual continues to meet the initial approval criteria; **AND** 2. Documentation indicating disease response to treatment, by stabilization of disease and decrease in size of tumor or tumor spread.			
Pembrolizumab and Berahyaluronidase alfa-pmph (e.g., Keytruda Qlex)	2026003	New policy effective May 20, 2026.	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2026003
Paliperidone Palmitate (e.g., Long-acting Injectables Invega Sustenna & Invega Trinza, Erzofri)	2016021	Prior approval banner statement will be removed effective May 20, 2026.	No	May 20, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016021