

PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	POLICY NUMBER	CRITERIA CHANGE	MATERIAL AMENDMENT	EFFECTIVE DATE	LINK TO FULL POLICY
Lurbinectedin (e.g., Zepzelca)	2021001	<p>Continuation coverage criteria for metastatic small cell lung cancer updated.</p> <ol style="list-style-type: none"> 1. Individual continues to meet the initial approval criteria; AND 2. Submission of clinical documentation showing stability and/or improvement in condition (e.g., lowered or stabilized tumor volume, decreased number of metastatic lesions, improvement in symptoms and quality of life). <p>FDA labeled indication for extensive-stage small cell lung cancer added.</p> <p>INITIAL APPROVAL:</p> <ol style="list-style-type: none"> 1. Individual is diagnosed with extensive-stage small cell lung cancer (EX-SCLC) (Zepzelca, 2025); AND 2. Individual is an adult (Zepzelca, 2025); AND 3. Individual is using in combination with atezolizumab or atezolizumab with hyaluronidase for maintenance treatment (Zepzelca, 2025); AND 4. Individual has not experienced disease progression after first-line induction therapy with atezolizumab (or atezolizumab with hyaluronidase), carboplatin and etoposide (Zepzelca, 2025); AND 5. Lurbinectedin is being dosed according to the FDA guidelines. <p>CONTINUATION OF THERAPY:</p> <ol style="list-style-type: none"> 1. Submission of clinical documentation showing stability and/or improvement in condition (e.g., lowered or stabilized tumor volume, decreased number of metastatic lesions, improvement in symptoms and quality of life); AND 	No	3/16/2026	https://insideblueapps/coverage/report.aspx?policyNumber=2021001

		2. Lurbinectedin is being dosed according to the FDA guidelines.			
Ziv-aflibercept (e.g., Zaltrap)	2017003	<p>Coverage criteria updated.</p> <p>Off-label Indications</p> <p>The use of this drug for off-label indications not listed below is subject to policy 2000030.</p> <p>INITIAL APPROVAL:</p> <ol style="list-style-type: none"> 1. Colon Cancer: <ol style="list-style-type: none"> a. Second-line and subsequent therapy for progression of advanced or metastatic disease (proficient mismatch repair/microsatellite-stable [pMMR/MSS] or ineligible for or progressed on checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., TMB greater than 50 mut/Mb]) in combination with irinotecan or with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, if not previously given, in individuals not previously treated with irinotecan-based therapy (NCCN 2A); OR b. Initial treatment for individuals with unresectable metachronous metastases (proficient mismatch repair/microsatellite-stable [pMMR/MSS]; deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., TMB greater than 50 mut/Mb] and individual is not a candidate for immunotherapy) and previous FOLFOX (fluorouracil, 	No	3/16/2026	https://insideblueapps/coverage/report.aspx?policyNumber=2017003

		<p>leucovorin, and oxaliplatin) or CAPEOX (capecitabine and oxaliplatin) within the past 12 months (NCCN 2A):</p> <ul style="list-style-type: none"> i. In combination with irinotecan; OR ii. In combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen; OR <p>2. Rectal Cancer:</p> <ul style="list-style-type: none"> a. Initial treatment for individuals with unresectable metachronous metastases (proficient mismatch repair/microsatellite-stable [pMMR/MSS] or deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., TMB greater than 50 mut/Mb] and are not candidates for immunotherapy) and previous FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CAPEOX (capecitabine and oxaliplatin) within the past 12 months (NCCN 2A): <ul style="list-style-type: none"> i. In combination with irinotecan; OR ii. In combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen; OR b. Second-line and subsequent therapy for progression of advanced or metastatic disease (proficient mismatch repair/microsatellite-stable [pMMR/MSS] or ineligible for or progressed on checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., TMB greater than 			
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		<p>50 mut/Mb]) in combination with irinotecan or with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, if not previously given, in individuals not previously treated with irinotecan-based therapy.</p> <p>CONTINUATION OF THERAPY:</p> <ol style="list-style-type: none"> 1. Individual has been previously approved and received Ziv-aflibercept (e.g., Zaltrap) through a medical benefit in the previous year or the individual has previously met all indication-specific criteria for coverage; AND 2. Individual has not progressed while receiving treatment with ziv-aflibercept. 			
Atezolizumab and Atezolizumab with Hyaluronidase (e.g., Tecentriq and Tecentriq Hybreza)	2016016	<p>Coverage criteria updated for Atezolizumab (e.g., Tecentriq).</p> <p>FDA labeled indications for small cell lung cancer updated to include in combination with lurbinectedin, for the maintenance treatment of adult individuals with ES-SCLC whose disease has not progressed after first-line induction therapy with atezolizumab (e.g., Tecentriq) or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide.</p> <p>Off-label indications updated to include thymomas and thymic carcinomas, chronic lymphocytic leukemia/small lymphocytic lymphoma-histologic transformation, bladder cancer-primary carcinoma of the urethra, and colon cancer.</p> <p>Continuation criteria added for off-label indications.</p> <p>Coverage criteria updated for Atezolizumab with Hyaluronidase (e.g., Tecentriq Hybreza).</p> <p>FDA labeled indications for small cell lung cancer updated to include in combination with lurbinectedin, for the maintenance treatment of adult individuals with ES-SCLC whose disease has not progressed after first-line induction therapy with atezolizumab</p>	No	3/16/2026	https://insideblueapps/coverage/report.aspx?policyNumber=2016016

		<p>with hyaluronidase (e.g., Tecentriq Hybreza) or intravenous atezolizumab, and carboplatin plus etoposide.</p> <p>FDA labeled indication for alveolar soft part sarcoma updated to include pediatric individuals (12 years of age and older who weigh 40 kg or greater).</p> <p>Off-label indications updated to include thymomas and thymic carcinomas, chronic lymphocytic leukemia/small lymphocytic lymphoma-histologic transformation, bladder cancer-primary carcinoma of the urethra, and colon cancer.</p> <p>Continuation criteria added for off-label indications.</p>			
Elivaldogene autotemcel (e.g., Skysona)	2023007	<p>Redundancy for criterion, “Elivaldogene autotemcel (e.g., Skysona) must be prescribed by or in consultation with a physician who specializes in the treatment of adrenoleukodystrophy (ALD)”, removed as this is stated in the banner statement, “The use of this drug/therapy requires documentation of direct involvement and ordering by a physician with expertise in specified condition and in a center approved for administration of CAR-T or gene product.”</p> <p>Policy guidelines updated to include acute myeloid leukemia as hematologic malignancy warning, “the individual should receive periodical monitoring for hematological malignancies, including Myelodysplastic Syndrome (MDS) and acute myeloid leukemia.”</p>	No	3/16/2026	https://insideblueapps/coverage/report.aspx?policyNumber=2023007
Tafasitamab-cxix (e.g., Monjuvi)	2021005	<p>FDA labeled continuation coverage criteria updated.</p> <p>Moved criterion for “Absence of unacceptable toxicity from the drug, including myelosuppression, infections, and anaphylactic reactions,” under policy guidelines.</p> <p>Off-label indication for initial approval of B-cell lymphomas updated.</p>	No	3/16/2026	https://insideblueapps/coverage/report.aspx?policyNumber=2021005

		<p>Classic follicular lymphoma as second-line and subsequent therapy in combination with lenalidomide and rituximab for no response, relapsed, or progressive disease individuals with indication for treatment (greater than or equal to 1 prior systemic therapy including an anti CD20 monoclonal antibody).</p> <p>Off-label continuation coverage criteria updated.</p> <p>Moved criterion for “Absence of unacceptable toxicity from the drug, including myelosuppression, infections, and anaphylactic reactions,” under policy guidelines.</p>			
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