

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><b>Continuation coverage criteria for metastatic small cell lung cancer updated.</b></p> <ol style="list-style-type: none"> <li>1. Individual continues to meet the initial approval criteria; <b>AND</b></li> <li>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).</li> </ol> <p><b>FDA labeled indication for extensive-stage small cell lung cancer added.</b></p> <p><b>INITIAL APPROVAL:</b></p> <ol style="list-style-type: none"> <li>1. Individual is diagnosed with extensive-stage small cell lung cancer (EX-SCLC) (Zepzelca, 2025); <b>AND</b></li> <li>2. Individual is an adult (Zepzelca, 2025); <b>AND</b></li> <li>3. Individual is using in combination with atezolizumab or atezolizumab with hyaluronidase for maintenance treatment (Zepzelca, 2025); <b>AND</b></li> <li>4. <b>Individual has not experienced disease progression</b> after first-line induction therapy with atezolizumab (or atezolizumab with hyaluronidase), carboplatin and etoposide (Zepzelca, 2025); <b>AND</b></li> <li>5. Lurbinectedin is being dosed according to the FDA guidelines.</li> </ol> <p><b>CONTINUATION OF THERAPY:</b></p> <ol style="list-style-type: none"> <li>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); <b>AND</b></li> </ol>	No	3/16/2026	<a href="https://insideblueapps/coverage/report.aspx?policyNumber=2021001">https://insideblueapps/coverage/report.aspx?policyNumber=2021001</a>

		<p>2. Lurbinectedin is being dosed according to the FDA guidelines.</p>			
Ziv-aflibercept (e.g., Zaltrap)	2017003	<p><b>Coverage criteria updated.</b></p> <p><b>Off-label Indications</b></p> <p><b>The use of this drug for off-label indications not listed below is subject to policy 2000030.</b></p> <p><b>INITIAL APPROVAL:</b></p> <ol style="list-style-type: none"> <li>1. Colon Cancer: <ul style="list-style-type: none"> <li>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); <b>OR</b></li> <li>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,</li> </ul> </li> </ol>	No	3/16/2026	<a href="https://insideblueapps/coverage/report.aspx?policyNumber=2017003">https://insideblueapps/coverage/report.aspx?policyNumber=2017003</a>

		<p>leucovorin, and oxaliplatin) or CAPEOX (capecitabine and oxaliplatin) within the past 12 months (NCCN 2A):</p> <ul style="list-style-type: none"> <li>i. In combination with irinotecan; <b>OR</b></li> <li>ii. In combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen; <b>OR</b></li> </ul> <p><b>2. Rectal Cancer:</b></p> <ul style="list-style-type: none"> <li>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):</li> </ul> <ul style="list-style-type: none"> <li>i. In combination with irinotecan; <b>OR</b></li> <li>ii. In combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen; <b>OR</b></li> </ul> <ul style="list-style-type: none"> <li>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</li> </ul>		
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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><b>CONTINUATION OF THERAPY:</b></p> <ol style="list-style-type: none"> <li>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; <b>AND</b></li> <li>2. Individual has not progressed while receiving treatment with ziv-aflibercept.</li> </ol>			
Atezolizumab and Atezolizumab with Hyaluronidase (e.g., Tecentriq and Tecentriq Hybreza)	2016016	<p><b>Coverage criteria updated for Atezolizumab (e.g., Tecentriq).</b></p> <p>FDA labeled indications for small cell lung cancer updated to include in combination with lorbrena, 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><b>Coverage criteria updated for Atezolizumab with Hyaluronidase (e.g., Tecentriq Hybreza).</b></p> <p>FDA labeled indications for small cell lung cancer updated to include in combination with lorbrena, 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	<a href="https://insideblueapps/coverage/report.aspx?policyNumber=2016016">https://insideblueapps/coverage/report.aspx?policyNumber=2016016</a>

		<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	<a href="https://insideblueapps/coverage/report.aspx?policyNumber=2023007">https://insideblueapps/coverage/report.aspx?policyNumber=2023007</a>
Tafasitamab-cxix (e.g., Monjuvi)	2021005	<p><b>FDA labeled continuation coverage criteria updated.</b></p> <p>Moved criterion for “Absence of unacceptable toxicity from the drug, including myelosuppression, infections, and anaphylactic reactions,” under policy guidelines.</p> <p><b>Off-label indication for initial approval of B-cell lymphomas updated.</b></p>	No	3/16/2026	<a href="https://insideblueapps/coverage/report.aspx?policyNumber=2021005">https://insideblueapps/coverage/report.aspx?policyNumber=2021005</a>

		<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><b>Off-label continuation coverage criteria updated.</b></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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