

Policy Name	Policy Number	Scope
Trilaciclib [Cosela]	MP-RX-FP-173-25	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
Service Category		
<input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B Drug		
Service Description		
<p>This document addresses the use of Trilaciclib [Cosela], a drug approved by the Food and Drug Administration (FDA) for the treatment of incidence of chemotherapy-induced myelosuppression in adults receiving certain types of chemotherapy for extensive-stage small cell lung cancer (ES-SCLC).</p>		
Background Information		
<p>The FDA approved indication for Cosela is to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for ES-SCLC.</p>		
<u>Dosing and Administration</u>		
<p>The recommended dose of Cosela is 240 mg/m² per dose. It is administered as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered. The interval between doses of Cosela on sequential days should not be greater than 28 hours.</p>		
<u>Missed Treatment Session(s):</u>		
<p>If Cosela dose is missed, discontinue chemotherapy on the day the Cosela dose was missed. Consider resuming both Cosela and chemotherapy on the next scheduled day for chemotherapy. Discontinuation of Treatment: If Cosela is discontinued, wait 96 hours from the last dose of COSELA before resumption of chemotherapy only.</p>		
<u>NCCN Guidelines</u>		
<p>In the updated NCCN guidelines for Hematopoietic Growth Factors, Cosela is recommended in only disease settings and chemotherapy regimens with a high risk (>20%) or intermediate risk (10-20%) for febrile neutropenia.</p>		
<u>Definitions and Measures</u>		
<ul style="list-style-type: none"> •CDK: Cyclin-dependent kinase inhibitor is any chemical that inhibits the function of CDKs. They are used to treat cancers by preventing over proliferation of cancer cells. •Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals. •Extensive-stage Small cell lung cancer (ES-SCLC): Occurs when the cancer has spread to both lungs or is detectable beyond the lungs. •Myelosuppression: Also referred to as bone marrow suppression, is a decrease in bone marrow activity resulting in reduced production of blood cells. This condition is a common side effect of chemotherapy. •Small cell lung cancer (SCLC): A fast-growing type of lung cancer. This aggressive form of lung cancer most commonly occurs in smokers. About 13% of people diagnosed with lung cancer have SCLC. 		

Medical Policy

Healthcare Services Department

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Applicable Codes		
<p>The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.</p>		
HCPCS	Description	
J1448	Injection, trilaciclib, 1 mg	
ICD-10	Description	
C34.00-C34.92	Malignant neoplasm of bronchus and lung	

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Trilaciclib [Cosela]

A. Criteria For Initial Approval

- i. Individual is 18 years of age or older (Label, NCCN 2A); **AND**
- ii. Individual has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND**
- iii. Individual is using to decrease the incidence of chemotherapy-induced myelosuppression; **AND**
- iv. Individual is using prior to a platinum/etoposide-containing regimen or topotecan containing regimen; **AND**
- v. Individual has an ECOG status of 0-2.

B. Criteria For Continuation of Therapy

- i. MMM considers continuation of **Trilaciclib [Cosela]** therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity, and the recommended duration of therapy has not been exceeded.

C. Authorization Duration

- i.
 - a. Initial Approval Duration: 6 months
 - b. Reauthorization Approval Duration: 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Requests for Cosela may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Cosela (trilaciclib)- Intravenous Solution Reconstituted 300 MG	240 mg/m ² per dose

Reference Information

1. 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 9, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 15, 2024
 - i. Hematopoietic Growth Factors. V3.2024. Revised January 30, 2024.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception 6/9/2025	Elevance Health's Medical Policy adoption	7/17/2025	8/8/2025