

Utilization Management and Clinical Medical Policy

Policy Name: Trilaciclib [Cosela®]	Policy Number: MP-RX-FP-173-25	Scope: <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	Origination Date: 8/8/2025 Last Review Date: 5/6/2026	Effective Date: 5/6/2026 Frequently Revision: Annual
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Service Category:

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| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Other: Part B Drugs |

Service Description:

This document addresses the use of Trilaciclib [Cosela®], a kinase inhibitor 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).

Background Information:

Cosela is an inhibitor of the cyclin-dependent kinase (CDK) 4 and CDK 6 enzymes. 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.

Dosing and Administration

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.

Missed Treatment Session(s): 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.

NCCN Guidelines

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.

Definitions and Measures

- 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.

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- 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.

Approved Indications

- A. Decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

Other Uses

- A. See background section above.

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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.

Trilaciclib (Cosela®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient’s diagnosis for the drug and confirming that the patient has met **all** approval criteria.*)

- 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. The following information should be submitted for reauthorization:
 - A. A current oncology note documenting the patient’s response to treatment showing no progression of disease.
 - B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

- i. Initial Approval Duration: 6 months
- ii. 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 *Trilaciclib [Cosela]* may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

- i. N/A

B. 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

Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
C34.00-C34.92	C34.00-C34.92
D61.810	Antineoplastic chemotherapy induced pancytopenia
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.9	Neutropenia, unspecified
T45.1X5A- T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs

HCPCS Codes:

Codes	Description
J1448	Injection, trilaciclib, 1 mg

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Reference Information:

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 2, 2025.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 15, 2024
 - a. Hematopoietic Growth Factors. V1.2025. Revised October 11, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Added Cosela's Pharmacologic Category to policy description, Coding Reviewed: Added ICD-10-CM D61.810, D70.1, D70.9, T45.1X5A-T45.1X5S. Administrative update to incorporate new template.	5/1/2026	5/6/2026
Policy Inception	Elevance Health's Medical Policy adoption	7/17/2025	8/8/2025