

Medical Drug Clinical Criteria

Subject: Cosela (trilaciclib)

Document #: CC-0192

Publish Date: 07/01/2025

Status: Reviewed

Last Review Date: 05/16/2025

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Overview

This document addresses the use of Cosela (trilaciclib). Cosela is an inhibitor of the cyclin-dependent kinase (CDK) 4 and CDK 6 enzymes. Cosela received priority review to reduce the incidence of chemotherapy-induced myelosuppression in adults receiving certain types of chemotherapy for extensive-stage small cell lung cancer (ES-SCLC).

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 overproliferation 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.

Clinical Criteria

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.

Cosela (trilaciclib)

Requests for Cosela (trilaciclib) may be approved if the following criteria are met:

- 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.

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

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1448 Injection, trilaciclib, 1 mg

ICD-10 Procedure

XW03377 Introduction of Trilaciclib into Peripheral Vein, Percutaneous Approach, New Technology Group 7
XW04377 Introduction of Trilaciclib into Central Vein, Percutaneous Approach, New Technology Group 7

ICD-10 Diagnosis

C34.00-C34.92 Malignant neoplasm of bronchus and lung
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
Z51.11 Encounter for antineoplastic chemotherapy

Document History

Reviewed: 05/16/2025

Document History:

- 05/16/2025 – Annual Review: No changes. Coding Reviewed: Added ICD-10-CM D61.810, D70.1, D70.9, T45.1X5A-T45.1X5S, Z51.11. Added ICD-10 procedure codes XW03377 and XW04377.
- 05/17/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Added NCCN reference to criteria. Removed HCPCS C9399. Added HCPCS C9078 Added ICD-10-CM C34.00-C34.92. Effective 10/1/2021 Added HCPCS J1448. Removed HCPCS J3490, C9078.
- 03/15/2021 – Annual Review: New clinical criteria document for Cosela. Coding reviewed: Added HCPCS J3490, C9399. All diagnosis pend.

References

1. 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.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. 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 April 2, 2025.
 - 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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