COSELA®
trilaciclib for injection 300 mg

PRIOR AUTHORIZATION
Supporting Documentation

BILLING AND CODING OPTIONS

HCPCS Code:
- J1448 – injection, trilaciclib, 1 mg

CPT® Code:
- 96365 – Therapeutic, prophylactic, and diagnostic injections and infusions; initial up to 1 hour

MEMBER INFORMATION

Patient name:

Date of birth:

Gender: ◯ Male ◯ Female

Insurance policy #:

Address:

Phone:

DIAGNOSIS / TREATMENT PLAN

Small cell lung cancer (SCLC)[1,2]
- Diagnosis Code (ICD-10-CM): C34.XX – Malignant neoplasm of bronchus and lung

◯ Confirmed immunohistochemistry (IHC) for SCLC[3]

Extensive-stage SCLC (ES-SCLC)[2,3]

◯ Identification of secondary tumor

Location of tumor:

Secondary diagnosis code:

Date of diagnosis:

Treatment plan[2,3]**:**

◯ Platinum etoposide-based chemotherapy

◯ Immune checkpoint inhibitors (ICIs)

◯ Topotecan

Line of therapy:

◯ 1st line ◯ 2nd/3rd line

PATIENT PERFORMANCE STATUS

◯ ECOG PS 0-2[2] ◯ KPS >70 ◯ KPS ≤70

CLINICAL INFORMATION[2]

◯ The requested medication is intended to be used to decrease the incidence of chemotherapy-induced myelosuppression

◯ Confirm COSELA® (trilaciclib) will not be used with a granulocyte colony-stimulating factor (G-CSF) as primary prophylaxis during cycle 1

PRODUCT INFORMATION

Request is for COSELA (Dose is per course of chemotherapy):

Frequency:

ADDITIONAL INFORMATION

◯ **Supporting documentation is included**

Completed form(s) and included required documentation, including supporting documentation for:

☐ Addressing myelosuppression risks

Included patient documentation:

☐ Patient information

☐ Rationale for use: myeloprotection of bone marrow

☐ Summary of patient diagnosis (ES-SCLC)

☐ Summary of patient history

☐ Secondary diagnosis code(s)

Included additional relevant information:

☐ Imaging results

☐ Pathology results

☐ Product prescribing information

☐ Peer-reviewed journal articles

☐ Nationally recognized guidelines

CPT=Current Procedural Terminology; ECOG PS=Eastern Cooperative Oncology Group Performance Status; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; KPS=Karnofsky Performance Status.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

COSELA is indicated 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 extensive-stage small cell lung cancer (ES-SCLC).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis and Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact Pharmacosmos Therapeutics at **1-800-790-4189** or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

This information is not comprehensive. Please see the full Prescribing Information.

References: 1. Centers for Medicare & Medicaid Services. 2026 ICD-10-CM Code Tables, Tabular and Index. Accessed November 10, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **2.** COSELA (trilaciclib). Prescribing Information. Pharmacosmos Therapeutics Inc.; 2025. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer V.2.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed November 11, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.