Utilization Review Policy 247

POLICY: Oncology (Injectable) – Cosela Utilization Management Medical Policy
- Cosela™ (trilaciclib intravenous infusion – G1 Therapeutics)

EFFECTIVE DATE: 06/01/2021
LAST REVISION DATE: 03/12/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Cosela, a cyclin dependent kinase (CDK) 4/6 kinase inhibitor, is indicated to **decrease the incidence of chemotherapy-induced myelosuppression** in adults when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (SCLC).[1]

The recommended dose of Cosela is 240 mg/m^2 per dose.[1] Cosela is administered prior to the start of chemotherapy on each day chemotherapy is given.[1] During Cycle 1 of the three Cosela pivotal studies, primary prophylactic granulocyte-colony stimulating factor (G-CSF) and erythropoiesis-stimulating agent (ESA) use was prohibited. Both ESAs and prophylactic G-CSF were allowed from Cycle 2, if clinically indicated. Therapeutic G-CSF, red blood cell, and platelet transfusions were allowed at any time during the studies as clinically indicated.

Guidelines

Cosela is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):[2,3]

- **Hematopoietic Growth Factors:** NCCN guidelines (version 1.2025 – October 11, 2024) recommend Cosela as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before (prophylactic granulocyte colony stimulating factor [G-CSF] may be administered after cycle 1) platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2A). It is also recommended as a prophylactic option to decrease the incidence of anemia and red blood cell transfusions when administered before platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2B).[2]
- **Small Cell Lung Cancer:** Under supportive care, the NCCN guidelines (version 4.2025 – January 13, 2025) note that Cosela or G-CSF may be used as prophylactic options to decrease the incidence of chemotherapy-induced myelosuppression when administering platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2A).[3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Cosela. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cosela as well as the monitoring required for adverse events and long-

term efficacy, approval requires Cosela to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cosela is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Small Cell Lung Cancer.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has extensive-stage disease; AND
   - **C)** The medication is used to decrease the incidence of chemotherapy-induced myelosuppression; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient will be receiving a platinum (carboplatin or cisplatin) and etoposide-containing chemotherapy regimen; OR
     - **ii.** Patient will be receiving a topotecan-containing regimen; AND
   - **E)** According to the prescriber, during the first cycle of chemotherapy, Cosela will not be co-administered with a granulocyte-colony stimulating factor (G-CSF) or an erythropoiesis-stimulating agent (ESA); AND
   - **F)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve one dose (240 mg/m^2) administered as an intravenous infusion for every day the chemotherapy regimen is given.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cosela is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cosela™ intravenous infusion [prescribing information]. Durham, NC: G1 Therapeutics; August 2023.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 10, 2025.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – January 13, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 10, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Small Cell Lung Cancer:** In the dosing criteria, removed the wording "up to" before 240 mg/m^2 to state "approve one dose (240 mg/m^2) administered as an intravenous infusion for every day the chemotherapy regimen is given.	03/22/2023
Annual Revision	No criteria changes.	03/20/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024

Selected Revision	**Small Cell Lung Cancer:** Added criterion that during the first cycle of chemotherapy, Cosela will not be co-administered with a colony stimulating factor or an erythropoiesis-stimulating agent, per the prescriber.	10/23/2024
Annual Revision	No criteria changes.	03/12/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025