Drug Coverage Policy

Effective Date.....07/15/2024
Coverage Policy Number.....IP0150
Policy Title..... Cosela

Oncology (Injectable) – Cosela

- Cosela™ (trilaciclib intravenous infusion – G1 Therapeutics)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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]

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

- **Hematopoietic Growth Factors:** NCCN guidelines (version 3.2024 – January 30, 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 2.2024 – November 21, 2023) 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]

Medical Necessity Criteria

Cosela is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Small Cell Lung Cancer.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, and E):
   - **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)** 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9078	Injection, trilaciclib, 1 mg (Code deleted 09/30/2021)
J1448	Injection, trilaciclib, 1 mg

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 3.2024 – January 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – November 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 15, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Trilaciclib Injection" to "Oncology (Injectable) – Cosela." **Small Cell Lung Cancer: Added** dosing information.	07/15/2024

The policy effective date is in force until updated or retired.