

## Cosela® (trilaciclib) (Intravenous)

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### I. Length of Authorization <sup>1</sup>

- Initial: Prior authorization validity will be provided initially for 4 months (120 days).
- Renewal: Prior authorization validity may be renewed every 4 months (120 days) thereafter.

### II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 3000 billable units (3000 mg) every 21 days

### III. Initial Approval Criteria <sup>1</sup>

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

#### Universal Criteria

- Will not be used concomitantly with colony stimulating factors for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy; **AND**

#### Chemotherapy-Induced Myelosuppression † ‡ <sup>1,2</sup>

- Member has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND**
- Used as prophylactic therapy to decrease the incidence of chemotherapy-induced myelosuppression; **AND**
- Member is undergoing myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
  - Topotecan-containing regimen

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

### IV. Renewal Criteria <sup>1</sup>

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions including phlebitis and thrombophlebitis, acute drug hypersensitivity reactions including facial edema and urticaria, interstitial lung disease/pneumonitis, etc.; **AND**
- Member continues to undergo myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
  - Topotecan-containing regimen

## V. Dosage/Administration <sup>1</sup>

| Indication                                                                                                                                                                                                                                     | Dose                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Prophylactic use to decrease the incidence of chemotherapy-induced myelosuppression                                                                                                                                                            | <ul style="list-style-type: none"> <li>• The recommended dose of Cosela is 240 mg/m<sup>2</sup> per dose. Administer as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.               <ul style="list-style-type: none"> <li>– The interval between doses of Cosela on sequential days should not be greater than 28 hours.</li> </ul> </li> </ul> |
| Regimens studied included: <ul style="list-style-type: none"> <li>• platinum/etoposide with Cosela administered on days 1, 2, &amp; 3 of a 21-day cycle</li> <li>• topotecan with Cosela administered on days 1-5 of a 21-day cycle</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J1448 – Injection, trilaciclib, 1 mg; 1 billable unit = 1 mg

### NDC:

- Cosela 300 mg single-dose vial: 73594-0101-xx

## VII. References

1. Cosela [package insert]. Morristown, NJ; Pharmacosmos Therapeutics Inc.; August 2025. Accessed June 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trilaciclib. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the

National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2026.

3. Lai AY, Sorrentino JA, Dragnev KH, et al. CDK4/6 inhibition enhances antitumor efficacy of chemotherapy and immune checkpoint inhibitor combinations in preclinical models and enhances T-cell activation in patients with SCLC receiving chemotherapy. J Immunother Cancer. 2020 Oct;8(2). pii: e000847. doi: 10.1136/jitc-2020-000847.
4. Weiss JM, Csoszi T, Maglakelidze M, et al; G1T28-02 Study Group. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase Ib/randomized phase II trial. Ann Oncol. 2019 Oct 1;30(10):1613-1621. doi: 10.1093/annonc/mdz278.
5. Hart LL, Ferrarotto R, Andric ZG, et al. Myelopreservation with Trilaciclib in Patients Receiving Topotecan for Small Cell Lung Cancer: Results from a Randomized, Double-Blind, Placebo-Controlled Phase II Study. Adv Ther. 2021 Jan;38(1):350-365. doi: 10.1007/s12325-020-01538-0. Epub 2020 Oct 29.

## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug               | Yes: Consider for PA  |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10   | ICD-10 Description                                                                |
|----------|-----------------------------------------------------------------------------------|
| D61.810  | Antineoplastic chemotherapy induced pancytopenia                                  |
| D70.1    | Agranulocytosis secondary to cancer chemotherapy                                  |
| D70.9    | Neutropenia, unspecified                                                          |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs initial encounter    |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter |

| ICD-10   | ICD-10 Description                                                   |
|----------|----------------------------------------------------------------------|
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs sequela |
| Z51.11   | Encounter for antineoplastic chemotherapy                            |
| Z51.12   | Encounter for antineoplastic immunotherapy                           |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI                                                                    | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ                                                      | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                                                                              | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                                                                                  | National Government Services, Inc. (NGS)          |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM                                                                  | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                                                                      | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                                                                                  | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA                                      |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA                                      |
| L (12)                                                        | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)                                                   | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS)          |
| 15                                                            | KY, OH                                                                                      | CGS Administrators, LLC                           |