

Cosela™ (trilaciclib) (Intravenous)

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I. Length of Authorization ¹

Coverage will be provided for 4 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Cosela 300 mg single-dose vial: 2 vials per dose
 - On days 1,2,3 (6 vials total) every 21 days when used in combination with etoposide
 - On days 1-5 (10 vials total) every 21 days when used in combination with topotecan

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

- 600 billable units (600 mg) per dose
 - On days 1,2,3 every 21 days when used in combination with etoposide
 - On days 1-5 every 21 days when used in combination with topotecan

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

Universal Criteria

- Will not be used concomitantly with colony stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc) for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy; **AND**

Chemotherapy Induced Myelosuppression † ^{1,2}

- Patient has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND**
- Patient is undergoing myelosuppressive chemotherapy with one of the following:
 - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
 - Topotecan-containing regimen

† FDA-labeled indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage for all other indications can be renewed based upon the following criteria:

- Patient 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, interstitial lung disease/pneumonitis, etc.; **AND**
- Patient 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 ¹

Indication	Dose
Prophylactic use to decrease the incidence of chemotherapy-induced myelosuppression	<ul style="list-style-type: none">• The recommended dose of Cosela is 240 mg/m² 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">– The interval between doses of Cosela on sequential days should not be greater than 28 hours.
Regimens studied included: <ul style="list-style-type: none">• platinum/etoposide with Cosela days 1, 2, & 3 of a 21-day cycle• topotecan with Cosela days 1-5 of a 21-day cycle	

VI. Billing Code/Availability Information

HCP Code:

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

NDC:

- Cosela 300 mg single-dose vial: 73462-0101-xx

VII. References

1. Cosela [package insert]. Durham, NC: G1 Therapeutics, Inc; February 2021. Accessed February 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trilaciclib. National Comprehensive Cancer Network, 2023. 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 February 2023.

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 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D61.81	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
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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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