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**

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- Topotecan-containing regimen

† FDA-labeled indication(s); ‡ Compendia recommended indication(s); Φ 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	• 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. – The interval between doses of Cosela on sequential days should not be greater than 28 hours.
Regimens studied included: • 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

HCPCS 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 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trilaciclib. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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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 2022.

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

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

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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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