



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Cosela™ (trilaciclib)

HCPCS: J1448

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Will not be used concomitantly with colony stimulating factors (e.g., pegfilgrastim and its biosimilars, filgrastim) for primary prophylaxis of febrile neutropenia
 - d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity limit: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Cosela is approved for use to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).
- Cosela works by inhibiting cyclin-dependent kinase 4/6, a type of enzyme that is involved in hematopoietic stem and progenitor cell (HSPC) proliferation. HSPCs in the bone marrow give rise to circulating neutrophils, red blood cells and platelets. It is designed to protect bone marrow from damage when administered prior to treatment with chemotherapy.
- SCLC accounts for about 10-15% of all lung cancers. In the United States, approximately 30,000 SCLC are treated annually. SCLC is an aggressive disease with about 2 out of 3 people diagnosed with extensive disease when their cancer is first found. The five-year survival rate is less than 2%.
- Standard of care chemotherapy regimens for ES-SCLC are highly myelosuppressive and can lead to increased risks of infection, severe anemia, bleeding, reduced or delayed dosing and hospitalizations. This is important as the patient population is often elderly with multiple comorbid conditions that increase the risk of chemotherapy.
- The approval of Cosela was based on 3 randomized, double-blind, placebo-controlled studies in 242 patients with ES-SCLC. Patients had an ECOG performance status of 0-2 and primary prophylactic granulocyte colony-stimulating factors (G-CSFs) was not allowed in cycle 1. The studies compared the proportion of patients with severe neutropenia and the duration of severe neutropenia in the first cycle of chemotherapy.
 - Across the 3 studies when given prior to chemotherapy, Cosela significantly decreased induced myelosuppression and the need for supportive care interventions.
 - Cosela showed statistically significant reductions in the duration of severe neutropenia, the percentage of patients who developed severe neutropenia, and the percentage of patients who required supportive care interventions, including G-CSFs, ESAs, and blood cell transfusions.
 - In the pivotal trial, 30% of patients treated with Cosela still required G-CSFs (47% with placebo) and 13% still required blood transfusions (21% with placebo).
 - Patients on Cosela across all studies experienced less $\geq$ grade 3 AEs, primarily due to a reduction in hematological $\geq$ grade 3 AEs, cycle delays, dose reductions and hospitalizations due to chemotherapy-induced myelosuppression or sepsis compared to placebo.
 - Cosela did not have a statistical effect on disease progression and survival.
- The 2025 National Comprehensive Cancer Network Guidelines for Hemopoietic Growth Factors treatment approaches for chemotherapy induced myelosuppression include growth factor agents to accelerate blood cell recovery after the bone marrow injury has occurred, Cosela as a myeloprotective agent given prior to myelosuppressive chemotherapy, along with antibiotics and transfusions as needed. Myeloid growth factors, G-CSFs, are used to reduce the incidence of febrile neutropenia. Erythropoiesis-stimulating agents (ESAs), are used to manage anemia.

References:

1. Cosela [prescribing information]. Durham, NC: G1 Therapeutics; August 2025.
2. Daniel D, Kuchava V, Bondarenko I, Ivashchuk O, Reddy S, Jaal J, Kudaba I, Hart L, Matitashvili A, Pritchett Y, Morris SR, Sorrentino JA, Antal JM, Goldschmidt J. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive-stage small cell lung cancer: A multicentre, 3andomized, double-blind, placebo-controlled Phase II trial. *Int J Cancer*. 2020 Dec 21.
3. Hart LL, Ferrarotto R, Andric ZG, Beck JT, Subramanian J, Radosavljevic DZ, Zaric B, Hanna WT, Aljumaily R, Owonikoko TK, Verhoeven D, Xiao J, Morris SR, Antal JM, Hussein MA. 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.
4. Weiss JM, Csoszi T, Maglakelidze M, Hoyer RJ, Beck JT, Domine Gomez M, Lowczak A, Aljumaily R, Rocha Lima CM, Boccia RV, Hanna W, Nikolinakos P, Chiu VK, Owonikoko TK, Schuster SR, Hussein MA, Richards DA, Sawrycki P, Bulat I, Hamm JT, Hart LL, Adler S, Antal JM, Lai AY, Sorrentino JA, Yang Z, Malik RK, Morris SR, Roberts PJ, Dragnev KH; 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. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 3.2026). 2025 Dec 5. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed on February 17, 2026.
6. Facts & Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.factsandcomparisons.com>. Accessed February 17, 2021.
7. IPD Analytics. New Drug Review. Cosela (trilaciclib). February 2021.

Policy History												
#	Date	Change Description										
1.6	Effective Date: 04/16/2026	Annual review of criteria was performed, no changes were made										
1.5	Effective Date: 04/10/2025	Annual review of criteria was performed, no changes were made										
1.4	Effective Date: 04/11/2024	Updated to remove the ECOG score requirement										
1.3	Effective Date: 04/06/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days and up to 6 months at a time										
1.2	Effective Date: 04/14/2022	Annual review of criteria was performed, no changes were made.										
1.1	Effective Date: 05/24/2021	UM medical management system update for BCNA, MAPPO, BCN, and BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 04/08/2021	New Policy										

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.