

Medical Policy:

Cosela™ (trilaciclib) powder for injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.337	March 20, 2024	April 2, 2021

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

Cosela, a cyclin dependent kinase (CDK) 4/6 kinase inhibitor, is indicated 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).

Length of Authorization

Initial coverage will be provided for six months.

Dosing Limits [Medical Benefit]

240 mg/m²/dose; administered prior to a platinum/etoposide- or topotecan-based regimen for extensive-stage small cell lung cancer

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

Guideline

I. INITIAL APPROVAL CRITERIA

1. Small Cell Lung Cancer- Chemotherapy Induced Myelosuppression

- A. Patient is 18 years of age or older; **AND**
- B. Cosela is prescribed by, or in consultation with, an oncologist; **AND**
- C. Patient has extensive-stage disease; **AND**
- D. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression; **AND**
- E. Patient meets **ONE** of the following criteria (i or ii):
 - i. Patient will be receiving platinum (carboplatin or cisplatin) and etoposide-containing chemotherapy regimen; **OR**
 - ii. Patient will be receiving topotecan-containing regimen

II. RENEWAL CRITERIA

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

- 1. Patient continues to meet Initial Criteria; **AND**
- 2. 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**
- 3. Patient continues to undergo myelosuppressive chemotherapy with one of the following:
 - A. Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
 - B. Topotecan-containing regimen

Limitations/Exclusions

- 1. Cosela is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

Applicable Procedure Codes

Code	Description
J1448	Injection, trilaciclib, 1mg

Applicable NDCs

Code	Description
73462-0101-01	Cosela (trilaciclib) 300 mg single dose vial

ICD-10 Diagnoses

Code	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
--------	---

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/20/2024	Annual Review: Updated dosing limits added renewal criteria
EmblemHealth & ConnectiCare	7/20/2023	Annual Review: Removed Codes: C34.00, C34.01, C34.02, C34.10, C34.11, C34.12 and C34.2. Added Codes: D61.81, D70.1, D70.9, T45.1X5a, T45.1X5D, T451X5S and Z51.11
EmblemHealth & ConnectiCare	4/08/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	4/2/2021	New Medical Policy

References

1. Cosela™ injection for intravenous use [prescribing information]. Durham, NC: G1 Therapeutics, Inc.; February 2021.
2. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – January 11, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 22, 2021.