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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 12, 2021
Subject:	Cosela	**Page:**	1 of 5

Last Review Date: March 8, 2024

Cosela

Description

Cosela (trilaciclib)

Background

Cosela (trilaciclib) is the first approved therapy indicated to reduce the frequency of chemotherapy-induced bone marrow suppression in adults receiving certain types of chemotherapy for extensive-stage small cell lung cancer. Cosela may protect bone marrow cells from damage caused by chemotherapy by inhibiting the cyclin-dependent kinases (CDK) 4 and 6. Hematopoietic stem and progenitor cells (HSPCs) in the bone marrow give rise to circulating neutrophils, red blood cells, and platelets. HSPC proliferation is dependent on CDK4/6 activity (1).

Regulatory Status

FDA-approved indication: Cosela is a kinase inhibitor 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 (1).

Cosela is administered as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered (1).

Cosela administration can cause injection-site reactions including phlebitis and thrombophlebitis. Patients should be monitored for signs and symptoms of injection-site reaction, phlebitis, and thrombophlebitis, including infusion-site pain and erythema during infusion (1).

Cosela administration can also cause acute drug hypersensitivity reactions, including facial edema and urticaria. Patients should be monitored for signs and symptoms of acute drug hypersensitivity reactions including facial, eye, and tongue edema, urticaria, pruritus, and anaphylactic reactions (1).

Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with Cosela. Patients should be monitored for pulmonary symptoms indicative of ILD/pneumonitis such as cough, dyspnea, and hypoxia (1).

Cosela can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with Cosela and for at least 3 weeks after the final dose (1).

The safety and effectiveness of Cosela in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cosela may be considered **medically necessary** if the conditions indicated below are met.

Cosela may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Extensive-stage small cell lung cancer
    a. Patient is being treated with a platinum/etoposide-containing regimen **OR** a topotecan-containing regimen
    b. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression

AND ALL of the following:

a. Prescriber agrees to monitor for injection-site reactions and acute drug hypersensitivity reactions
b. Prescriber agrees to monitor for pulmonary symptoms indicative of ILD/pneumonitis
c. **NOT** used in combination with granulocyte colony-stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc.) and/or erythropoiesis-stimulating agents (e.g., Epogen, Procrit, Aranesp, etc.) for primary prophylaxis of febrile neutropenia during cycle 1 of chemotherapy
d. Females of reproductive potential **ONLY:** patient will be advised to use effective contraception during treatment with Cosela and for at least 3 weeks after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Extensive-stage small cell lung cancer
   a. Patient is being treated with a platinum/etoposide-containing regimen **OR** a topotecan-containing regimen
   b. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression

AND ALL of the following:

a. Prescriber agrees to monitor for injection-site reactions and acute drug hypersensitivity reactions
b. Prescriber agrees to monitor for pulmonary symptoms indicative of ILD/pneumonitis.
c. Females of reproductive potential **ONLY:** patient will be advised to use effective contraception during treatment with Cosela and for at least 3 weeks after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Cosela (trilaciclib) is a transient inhibitor of CDK4 and 6. Hematopoietic stem and progenitor cells (HSPCs) in the bone marrow give rise to circulating neutrophils, red blood cells, and platelets. HSPC proliferation is dependent on CDK4/6 activity. Cosela 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. Cosela administration can cause injection-site reactions including phlebitis and thrombophlebitis; acute drug hypersensitivity reactions, including facial edema and urticaria; and severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis. Patients should be monitored closely. Cosela can cause fetal harm and female patients of reproductive potential should use an effective method of contraception during treatment with Cosela and for at least 3 weeks after the final dose. The safety and effectiveness of Cosela in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cosela while maintaining optimal therapeutic outcomes.

References

1. Cosela [package insert]. Durham, NC: G1 Therapeutics, Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Trilaciclib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 29, 2024.

Policy History

Date	Action
March 2021	Addition to PA

April 2021	Addition of initiation requirement for no dual therapy with colony-stimulating factor and/or erythropoiesis-stimulating agents as primary prophylaxis during cycle 1 of chemotherapy per FEP
June 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.