CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Trilaciclib (Cosela®)

Version: 1.0

EFFECTIVE DATE: 1/1/2024

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Trilaciclib (Cosela®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Trilaciclib (Cosela): Discussion

Trilaciclib is an inhibitor of cyclin-dependent kinase 4 and 6 (CDK 4/6). Hematopoietic stem and progenitor cells (HSPCs) in the bone marrow give rise to circulating neutrophils, red blood cells (RBCs), and platelets. HSPC proliferation is dependent on CDK4/6 activity.[1] Trilaciclib transiently arrests CDK4/6-dependent HSPCs in the G1 phase of the cell cycle during chemotherapy exposure, thereby protecting bone marrow function from chemotherapy-induced damage (myeloprotection or myelopreservation).[3]

Trilaciclib is approved by the Food and Drug Administration (FDA) 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).[1]

Trilaciclib is endorsed by the National Comprehensive Cancer Network (NCCN) as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before (prophylactic granulocyte colony-stimulating factor (G-CSF) may be administered after cycle 1) platinum/etoposide with or without immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for ES-SCLC.[2]

Trilaciclib can cause interstitial lung disease (ILD)/Pneumonitis.[1]

Trilaciclib: Definitions

- **Food and Drug Administration (FDA)** – The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN) -** An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN

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consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Trilaciclib: Policy

Trilaciclib will be considered for coverage when the following criteria are met:

Note: Coverage of trilaciclib will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Small Cell Lung Cancer (Extensive Stage)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Used as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before one of the following:
    a) Platinum/etoposide (with or without immune checkpoint inhibitor) containing regimens
    b) Topotecan-containing regimens

Note: Prophylactic G-CSF may be administered after cycle 1. [2]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Trilaciclib: References

1. Cosela (Trilaciclib®) Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214200s004lbl.pdf. Accessed May 30, 2023.
2. National Comprehensive Cancer Network Guidelines. Hematopoietic Growth Factors (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed May 30, 2023.
3. Exploratory composite endpoint demonstrates benefit of trilaciclib across multiple clinically meaningful components of myeloprotection in patients with small cell lung cancer. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8457063. Accessed May 30, 2023.

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Trilaciclib: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all inclusive and is subject to updates. In addition, codes listed are not a guarantee of payment.

CODE	DESCRIPTION
C34.00-C34.92	Malignant neoplasm of bronchus and lung
J1448	Trilaciclib (Cosela)

Trilaciclib: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	5/30/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	10/23/2023
6	Revision Changes:	

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