Original Effective Date: 04/28/2021
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C21205-A

Cosela (trilaciclib)

PRODUCTS AFFECTED

Cosela (trilaciclib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Small Cell Lung Cancer

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. SMALL CELL LUNG CANCER:
1. Documentation that the member has a diagnosis of extensive stage small cell lung cancer.
   NOTE: Extensive stage is defined as Stage IV (T any, N any, M 1a/b/c) or T3-4 due to

multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.
AND

2. Documentation of member's chemotherapy treatment plan indicating that member will be treated with a platinum/etoposide-containing regimen or a topotecan-containing regimen AND that trilaciclib will be administered within 28 hours on sequential days when chemotherapy is administered [DOCUMENTATION REQUIRED].
AND
3. For female members of childbearing potential, provider attests that member has had a negative pregnancy screening and has been counseled on the use of effective contraception during treatment and per FDA labeled recommendations. Note: Based on its mechanism of action, trilaciclib can cause fetal harm if administered to a pregnant woman.
AND
4. Documentation that member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2.
AND
5. Prescriber attests that use of trilaciclib is medically necessary and more appropriate for the member than the use of granulocyte colony stimulating factors (GCSF) and other supportive measures (e.g., erythropoiesis-stimulating agents [ESAs], transfusions) due to member specific risk factors for chemotherapy induced neutropenia or chemotherapy induced anemia (see Appendix).

CONTINUATION OF THERAPY:

A. SMALL CELL LUNG CANCER:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Documentation of clinical benefits to support continuation of treatment including positive response to therapy as evidenced by ONE of the following while treated with Cosela (trilaciclib):
   (a) Member did not experience prolonged neutropenia, defined as an absolute neutrophil count (ANC) less than 0.5 x 10^9 lasting more than 7 days
   (b) Member did not experience neutropenic infection or febrile neutropenia
   (c) Member did not experience Grade 3 thrombocytopenia (platelet count less than 50,000 cells/mm3) or have an increase in transfusions (platelet or red blood cells) during treatment period
   (d) Member did not require next chemotherapy cycle to be held due to myelosuppression or require more than one chemotherapy dose reduction due to myelosuppression
AND
3. Prescriber attests or clinical reviewer has found no evidence that the member has experienced any adverse reactions warranting discontinuation of treatment with Cosela (trilaciclib) (see Appendix).
AND
4. Documentation that members treatment plan continues to be a platinum/etoposide-containing regimen or a topotecan-containing regimen AND documentation of the number of cycles remaining [DOCUMENTATION REQUIRED].

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of Therapy: 6 months or maximum duration of planned chemotherapy, whichever is shorter

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an oncologist, hematologist, or other specialist treating cancer [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization

requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
240 mg/m^2 per dose, up to 3 doses for a platinum/etoposide-containing regimen per cycle OR up to 5 doses for a topotecan-containing regimen per cycle.

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Myeloprotective Agent

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Adverse Reactions requiring permanent discontinuation of Cosela:

- Grade 3 Injection Site Reactions: Ulceration or necrosis; severe tissue damage; operative intervention indicated
- Grade 4 Injection Site Reactions: Life-threatening consequences; urgent interventions indicated
- Grade 3 Acute Drug Hypersensitivity reactions: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL
- Grade 4 Acute Drug Hypersensitivity reactions: Life-threatening consequences; urgent interventions indicated
- Grade 3 Interstitial lung disease/pneumonitis: Severe symptoms; limiting self-care ADL; oxygen indicated.
- Grade 4 Interstitial lung disease/pneumonitis: Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)

Member risk factors for consideration of use of Granulocyte Colony Stimulating Factors[8] (MGF-2, -3, category 2A):

- Prior chemotherapy or radiation therapy
- Persistent neutropenia
- Bone marrow involvement by tumor
- Recent surgery and/or open wounds
- Liver Dysfunction (bilirubin >2.0)
- Renal Dysfunction (creatinine clearance <50)

- Age >65 years receiving full chemotherapy dose intensity
- Febrile neutropenia or dose-limiting neutropenic event

Member risk factors for chemotherapy induced anemia[2] (ANEM-2, category 2B):

- Progressive decline in hemoglobin with recent intensive chemotherapy or radiation
- Asymptomatic with comorbidities: cardiac disease, chronic pulmonary disease, or cerebral vascular disease

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Cosela (trilaciclib) is a kinase inhibitor which transiently inhibits CDK 4 and 6. Hematopoietic stem cell and progenitor cell (HSPC) proliferation is dependent on the CDK 4 and 6 activity. By transiently (up to 32 hours) arresting HSPC in the G1 phase of the cell cycle, Cosela exerts myeloprotective effects. Approximately 32 hours after the dose, the bone marrow resumes proliferation.

Trilaciclib was studied in three randomized, double blind, placebo-controlled trials, all in patients with extensive stage- small cell lung cancer (ES-SCLC). Study 1 (G1T28-05) administered trilaciclib prior to treatment with etoposide, carboplatin, and atezolizumab in patients (n=107) with a new diagnosis of ES-SCLC. In the study arm, Trilaciclib (n=54) was administered prior to chemotherapy on days 1, 2 and 3 of a 21-day cycle. Fewer patients required dose reductions of either etoposide (6% trilaciclib, 26% placebo) or carboplatin (2% trilaciclib, 25% placebo), compared to placebo.

Study 2 (G1T28-02) administered trilaciclib prior to treatment with etoposide and carboplatin in patients (n=77) with a new diagnosis of ES-SCLC who had not been previously treated with chemotherapy. In the study arm, Trilaciclib (n=39) was administered prior to chemotherapy on days1, 2 and 3 of a 21-day cycle. The rate of red blood cell transfusions was 0.5/100 weeks in the trilaciclib arm, compared to 1.9/100 weeks in the placebo arm (n=38).

Study 3 (G1T28-03) administered trilaciclib prior to treatment with topotecan in patients (n=61) with ES-SCLC who had been previously treated with chemotherapy. In the study arm, trilaciclib (n=32) was administered prior to topotecan on days 1 through 5 of a 21-day cycle, with treatment continued until disease progression. The mean duration of severe neutropenia was lower in the trilaciclib arm (mean 2 days, standard deviation 3.9 days) compared to placebo (mean 7 days, standard deviation 6.2 days). Additionally, the number and percentage of patients with severe neutropenia was lower in the trilaciclib arm (13, 40.6%) compared to placebo (22, 75.9%).

NCCN guidelines[9] state that trilaciclib may be used as a prophylactic option to decrease the incidence of chemotherapy induced myelosuppression when administered before platinum/etoposide with or without a checkpoint inhibitor or a topotecan containing regimen for ES-SCLC, or that granulocyte colony stimulating factors (G-CSF) may be administered after chemotherapy (category 2A, SCL-D). In the studies, trilaciclib was studied against placebo, not compared to alternative treatment. Additionally, patients who were treated with trilaciclib still required G-CSFs, but at a rate lower compared to placebo (35% trilaciclib, 67% placebo).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cosela (trilaciclib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Cosela (trilaciclib) include: a history of serious hypersensitivity to reactions to trilaciclib, concomitant use with certain OCT2, MATE1, and MATE-2K substrates where minimal concentration changes may lead to serious or life-threatening toxicities, pregnancy (known risk of fetal harm), and breastfeeding.

OTHER SPECIAL CONSIDERATIONS:

Cosela (trilaciclib) is administered 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.

If Cosela (trilaciclib) is discontinued, the member should wait 96 hours from the last dose of Cosela before resumption of chemotherapy only.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1448	Injection, trilaciclib, 1mg

AVAILABLE DOSAGE FORMS:
Cosela SOLR 300MG single-dose vial

REFERENCES

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3. National Comprehensive Cancer Network. 2022. Small Cell Lung Cancer (Version 2.2023). [online] Available at: <sclc.pdf (nccn.org) > [Accessed 11 December 2022].
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8. National Comprehensive Cancer Network. 2023. Hematopoietic Growth Factors (Version 2.2024). [online] Available at: <growthfactors.pdf (nccn.org)> [Accessed 14 December 2023].
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11. National Comprehensive Cancer Network. 2025. Small Cell Lung Cancer (Version 3.2025). [online] Available at: <sclc.pdf (nccn.org) > [Accessed 7 January 2025].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information References	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Drug Class Other Special Considerations References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Appendix Contraindications/Exclusions/Discontinuation References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file