Evolent Clinical Guideline 3034 for Cosela™ (trilaciclib)

Guideline Number:	Applicable Codes	
Evolent_CG_3034		
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STATEMENT

Purpose

To define and describe the accepted indications for Cosela (trilaciclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Extensive Stage Small Cell Lung Cancer (ES-SCLC)

- Cosela (trilaciclib) is not supported by Evolent Policy for use to prevent chemotherapy induced myelosuppression in extensive stage SCLC.
- **Rationale for the above policy position:** Based on a review of the 3 studies conducted on this drug, we noted that:
    - The incidence of febrile neutropenia was not used as an efficacy endpoint in any of the trials.
    - G-CSF use was allowed starting cycle 2 for all 3 trials. A significant proportion of patients received G-CSF in both the placebo and Cosela groups. The use of IV antibiotics was 22% in the Cosela group vs 28% in the placebo group-a non-significant difference in the trial using Cosela with topotecan.
    - There is no Level 1 evidence (randomized trial and/or meta-analysis) to support that Cosela + G-CSF therapy significantly decreases the risk of febrile neutropenia compared to G-CSF therapy alone.
    - With regards to anemia prevention, the rate of ESA use for anemia of chemotherapy was 3% in the Cosela group vs 5% in the placebo group-a non-significant difference-in the trial using a 3-drug regimen.
    - With regards to platelet transfusions: 8 patients received platelet transfusions in the Cosela group compared to 9 patients in the placebo group-a non-significant difference-in the trial using topotecan.

- Based on our review, the use of Cosela does not offer significant clinical benefits in terms of decreasing myelosuppression, over and above the use of G-CSF, and other supportive care (ESAs, platelet transfusions etc.).
- None of these studies showed an improvement in Progression-Free Survival (PFS) or Overall Survival (OS).

CONTRAINDICATIONS/WARNINGS

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

EXCLUSION CRITERIA

- Investigational use of Cosela (trilaciclib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J1448 - Injection, trilaciclib, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
March 2026	• Updated references
March 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1424 Cosela (trilaciclib) • Updated references
March 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care

coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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