Reference number(s)
4548-A

STANDARD MEDICARE PART B MANAGEMENT

COSELA (trilaciclib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
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 (ES-SCLC).

B. Compendial Use
Prophylaxis of chemotherapy-induced anemia

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Extensive-stage Small Cell Lung Cancer
Authorization of 6 months may be granted to decrease the incidence of chemotherapy-induced myelosuppression or anemia and red blood cell transfusions in adult patients with extensive-stage small cell lung cancer when all of the following criteria are met:
A. The member will be receiving either of the following chemotherapeutic regimens:
   1. A platinum/etoposide-containing regimen.
   2. A topotecan-containing regimen.
B. The requested medication will be given within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.

C. The member is receiving benefit from therapy.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Cosela.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Hematopoietic growth factors

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Cosela are covered as well as prophylaxis of chemotherapy-induced anemia in patients who will receive a platinum/etoposide-containing regimen or topotecan-containing regimen for ES-SCLC.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Cosela to decrease the incidence of anemia from chemotherapy can be found in the National Comprehensive Cancer Network's guideline for hematopoietic growth factors. The NCCN Guideline supports the use of Cosela as a prophylactic option to decrease the incidence of anemia and red blood cell transfusions when administered before platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

VI. REFERENCES

1. Cosela [package insert]. Durham, NC: G1 Therapeutics, Inc; February 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 3, 2023.