Clinical Policy Title:	trilaciclib
Policy Number:	RxA.682
Drug(s) Applied:	Cosela™
Original Policy Date:	04/16/2021
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
trilaciclib (Cosela™)	Myelosuppression, Chemotherapy-induced, prior to a platinum/etoposide or topotecan-containing regimen in patients with extensive-stage SCLC	240 mg/m^2/dose; administered prior to a platinum/etoposide- or topotecan-based regimen for extensive-stage SCLC. Trilaciclib infusion should be completed within 4 hours prior to the start of chemotherapy; administer trilaciclib on each day chemotherapy is administered.	240 mg/m^2 IV

Dosage Forms

- Injection: 300 mg of trilaciclib as a lyophilized cake in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Small cell lung cancer (must meet all):

1. Diagnosis of extensive-stage SCLC;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with an oncologist;
4. The medication is used to decrease the incidence of chemotherapy-induced myelosuppression;

5. Request meets one of the following (a or b):
   a. Cosela will be administered within 4 hours prior to start of platinum (carboplatin or cisplatin) and etoposide-containing chemotherapy regimen
   b. Cosela will be administered within 4 hours prior to start of topotecan-containing regimen;
6. Request meets one of the following (a or b):**
   a. Dose does not exceed 240 mg/m^2/dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   **Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Small cell lung cancer (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Request meets one of the following (a or b):**
   a. Dose does not exceed 240 mg/m^2/dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   **Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SCLC: Small Cell Lung Cancer

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym™)	Recommended starting dose: 5 mcg/kg SC or IV once daily Dose may be increased in increments of 5 mcg/kg for each chemotherapy cycle, according to the duration and severity of the absolute neutrophil count (ANC) nadir. Stop therapy if the ANC increases beyond 10,000/mm3 Do not administer 24 hours before and after chemotherapy	30 mcg/kg/day [IV] or 24 mcg/kg/day [SC]
Tbo-filgrastim (Granix®)	5 mcg/kg SC or IV once daily	5 mcg/kg/day

Drug Name	Dosing Regimen	Maximum Dose
pegfilgrastim (Neulasta®, Neulasta Onpro®) pegfilgrastim-apgf (Nyvepria™) pegfilgrastim-jmdb (Fulphila®) pegfilgrastim-cbqv (Udenyca®) pegfilgrastim-bmez (Ziextenzo™)	6 mg administered SC once per chemotherapy cycle. Do not administer between 14 days before or 24 hours after administration of cytotoxic chemotherapy.	6 mg/dose
epoetin alfa (Epogen®, Procrit®) epoetin alfa-epbx (Retacrit™)	Initiate treatment only if Hb <10 g/dL and anticipated duration of myelosuppressive chemotherapy is at least 2 additional months. Titrate dosage to use the minimum effective dose that will maintain a Hb level sufficient to avoid RBC transfusions. Discontinue erythropoietin following completion of chemotherapy. SubQ: Initial dose: 150 units/kg 3 times a week or 40,000 units once weekly until completion of chemotherapy.	Varies depending on indication, frequency of administration, and individual response; for patients with cancer, doses up to 60,000 units IV weekly until completion of chemotherapy.

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Patients with a history of serious hypersensitivity reactions to Cosela™

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Injection-Site Reactions, Including Phlebitis and Thrombophlebitis: Monitor for signs and symptoms of injection-site reactions, including phlebitis and thrombophlebitis during infusion. Stop infusion and permanently discontinue Cosela™ for severe or life-threatening reactions.

- Acute Drug Hypersensitivity Reactions: Monitor for signs and symptoms of acute drug hypersensitivity reactions, including edema (facial, eye, and tongue), urticaria, pruritus, and anaphylactic reactions. Withhold Cosela™ for moderate reactions, and permanently discontinue for severe or life-threatening reactions.

- Interstitial Lung Disease (ILD)/Pneumonitis: Patients treated with CDK4/6 inhibitors should be monitored for pulmonary symptoms indicative of ILD/pneumonitis. Interrupt and evaluate patients with new or worsening symptoms suspected to be due to ILD/pneumonitis. Permanently discontinue konsi e™ in patients with recurrent symptomatic or severe/life-threatening ILD/pneumonitis.

- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

References

1. Cosela™ (trilaciclib) [prescribing information]. Durham; NC: G1 Therapeutics, Inc., February 2021. Available at: https://www.g1therapeutics.com/cosela/pi/. Accessed on April 19, 2021.
2. National Comprehensive Cancer Network. Small cell lung Cancer Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc_blocks.pdf. Accessed April 19, 2021.
3. IPD Analytics. Cosela™ (trilaciclib). Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Cosela. Updated in February 2021. Accessed April 19, 2021.
4. Lexicomp. [Internet database]. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: https://online.lexi.com/lco/action/home . Accessed April 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/22/2021	06/10/2021