Clinical Policy Title:	trilaciclib
Policy Number:	RxA.682
Drug(s) Applied:	Cosela™
Original Policy Date:	04/16/2021
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Cosela™ will not be used concomitantly with colony stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc) for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed intravenous 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 the member has 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 intravenous 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

References

1. National Comprehensive Cancer Network. Small cell lung Cancer. Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc_blocks.pdf. Accessed February 1, 2023.
2. National Comprehensive Cancer Network. Hematopoietic Growth Factors. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed February 1, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/22/2021	06/10/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	02/01/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.6: Updated to include new combination therapy criteria Cosela™ will not be used concomitantly with colony stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc) for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy. 2. Reference were reviewed and updated.	02/01/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023