RXADVANCE
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Southborough, MA 01772

Clinical Policy Title:	lurbinectedin
Policy Number:	RxA.642
Drug(s) Applied:	Zepzelca®
Original Policy Date:	07/26/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Zepzelca® is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Lurbinectedin (Zepzelca®)	Metastatic SCLC with disease progression on or after platinum-based chemotherapy	3.2 mg/m^2 once every 21 days until disease progression or unacceptable toxicity	3.2 mg/m^2 per 21-day cycle

Dosage Forms

- For IV injection: 4 mg lyophilized powder 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.

I. Initial Approval Criteria

A. Metastatic Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced, or metastatic SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Must have current or prior treatment with platinum-based chemotherapy;
5. Trial and failure of topotecan PO or IV unless contraindicated or clinically adverse effects are experienced; *
6. Request meets one of the following (a or b): *
    a. Dose does not exceed 3.2 mg/m^2 per day;

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. Metastatic Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Any dose adjustments meet one of the following (a or b): *
   a. Dose does not exceed 3.2 mg/m^2 per day;
   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
NCCN: National Comprehensive Cancer Network
SCLC: Small Cell Lung Cancer

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Maximum Dose
Topotecan (Hycamtin®)	PO: 2.3 mg/m^2/day for 5 consecutive days every 21 days	2.3 mg per day
	IV: 1.5 mg/m^2/day for 5 consecutive days every 21 days	1.5 mg per day

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):
  - None.
- Boxed Warning(s):

- None.

APPENDIX D: General Information
Strong/moderate CYP3A inducers and inhibitors: Avoid coadministration.

Zepzelca® has not been studied in patients with the following conditions: Central nervous system (CNS) involvement, grade ≥3 dyspnea, daily intermittent oxygen requirement, hepatitis or cirrhosis, and immunocompromised patients. Caution should be exercised in using Zepzelca with these patients.

References

1. Zepzelca Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc; June 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213702s000lbl.pdf. Accessed July 26, 2020.
2. National Comprehensive Cancer Network Guidelines. Small Cell Lung Cancer Version 4.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Published July 7, 2020. Accessed July 26, 2020.
3. Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. Lancet Oncol. 2020 May;21(5):645–654.
4. Lurbinectedin. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. http://online.lexi.com/. Updated July 23, 2020. Accessed July 26, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/27/2020	09/14/2020