Clinical Policy: Lurbinectedin (Zepzelca)

Reference Number: PA.CP.PHAR.500
Effective Date: 10/2020
Last Review Date: 07/2023

Coding Implications
Revision Log

Description
Lurbinectedin (Zepzelca™) is an alkylating drug.

FDA Approved Indication(s)
Zepzelca is 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)

Policy/Criteria
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Zepzelca is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of advanced or metastatic SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as single-agent therapy;
5. Disease has progressed on or after platinum-containing regimen (e.g., cisplatin, carboplatin);
6. Request meets one of the following (a or b):
   a. Dose does not exceed 3.2 mg/m^2 every 21 days;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy;
3. Prescribed as single-agent therapy;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 3.2 mg/m^2 every 21 days;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cisplatin- or carboplatin-containing chemotherapy	Varies	Varies

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
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SCLC	3.2 mg/m^2 IV every 21 days	3.2 mg/m^2 per 21 days

VI. Product Availability

Single-dose vial: 4 mg

VII. References

1. Zepzelca Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2022. Available at https://www.zepzelca.com. Accessed April 13, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed May 7, 2023.
3. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed May 7, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9223	Injection, lurbinectedin, 0.1 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; removed option to bypass platinum containing regimen if contraindicated or clinically significant adverse effects are experienced per prescribing information; references reviewed and updated.	07/2022
3Q 2023 annual review: added monotherapy requirement per NCCN; references reviewed and updated.	07/2023