## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 08/01/2021** |
| **Policy Number: PA.CP.PHAR.500** | **Effective Date: 10/2020**<br>**Revision Date: 07/2021** |
| **Policy Name: Lurbinectedin (Zepzelca)** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

3Q 2021 annual review: no significant changes; references reviewed and updated.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Venkateswara R. Davuluri, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Lurbinectedin (Zepzelca)

Reference Number: PA.CP.PHAR.500
Effective Date: 10/2020
Last Review Date: 07/2021

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.

**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 health plans affiliated with 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. Failure of a platinum-containing regimen (e.g., cisplatin, carboplatin), unless clinically significant adverse effects are experienced or all are contraindicated;
5. 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).*

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

**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. 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).*

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

**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.; June 2020. Available at https://www.zepzelca.com. Accessed May 12, 2021.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed May 12, 2021.
3. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed May 12, 2021.

**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 |