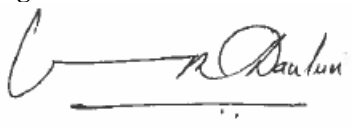


## Prior Authorization Review Panel

### 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.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 08/01/2021</b>
<b>Policy Number: PA.CP.PHAR.500</b>	<b>Effective Date: 10/2020</b> <b>Revision Date: 07/2021</b>
<b>Policy Name: Lurbinectedin (Zepzelca)</b>	
<p><b>Type of Submission – <u>Check all that apply:</u></b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> New Policy</li> <li><input checked="" type="checkbox"/> Revised Policy*</li> <li><input type="checkbox"/> Annual Review - No Revisions</li> <li><input type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i></li> </ul>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p style="margin-top: 20px;">3Q 2021 annual review: no significant changes; references reviewed and updated.</p>	
<b>Name of Authorized Individual (Please type or print):</b>  Venkateswara R. Davuluri, MD	<b>Signature of Authorized Individual:</b>  

## 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  $\geq$  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<sup>2</sup> 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<sup>2</sup> 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 <sup>2</sup> IV every 21 days	3.2 mg/m <sup>2</sup> 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](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