

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Zepzelca Prior Authorization Policy

- Zepzelca[™] (lurbinectedin intravenous infusion – Jazz)

REVIEW DATE: 06/26/2024

OVERVIEW

Zepzelca, an alkylating drug, is indicated for the treatment of metastatic **small cell lung cancer** in adults with disease progression on or after platinum-based chemotherapy.¹ 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).

Guidelines

The National Comprehensive Cancer Network (NCCN) Small Cell Lung Cancer guidelines (version 3.2024 – June 11, 2024) recommend Zepzelca as a single agent for the treatment of relapsed disease following a complete or partial response, or stable disease with initial treatment, or for the treatment of primary progressive disease.^{2,3}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zepzelca. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zepzelca as well as the monitoring required for adverse events and long-term efficacy, approval requires Zepzelca to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zepzelca is recommended in those who meet the following:

FDA-Approved Indication

1. **Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has metastatic disease; AND
 - C) Patient has previously received platinum-based chemotherapy; AND
Note: Examples of platinum medications include cisplatin and carboplatin.
 - D) Zepzelca is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zepzelca is not recommended in the following situations:

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1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zepzelca intravenous infusion [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; July 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 18, 2024. Search term: lurbinectedin.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – June 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 18, 2024.