Utilization Review Policy 243

POLICY: Oncology (Injectable) – Zepzelca Utilization Management Medical Policy
- Zepzelca™ (lurbinectedin intravenous infusion – Jazz)

EFFECTIVE DATE: 01/01/2021
LAST REVISION DATE: 06/04/2025

COVERAGE CRITERIA FOR: All UCare Plans

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 4.2025 – January 13, 2025) 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 medical benefit coverage of Zepzelca. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 primary progressive, relapsed, or metastatic disease; AND
C) Patient has previously received platinum-based chemotherapy; AND
Note: Examples of platinum medications include cisplatin and carboplatin.
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 3.2 mg/m^2 administered by intravenous infusion no more frequently than once every 21 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zepzelca is not recommended in the following situations:

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. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 6, 2025. Search term: lurbinectedin.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – January 13, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 6, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/28/2023
Annual Revision	**Small Cell Lung Cancer:** Added requirement that the patient is ≥ 18 years of age.	06/26/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Small Cell Lung Cancer:** Added "primary progressive" and "relapsed" disease as qualifiers for approval.	06/04/2025