VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Zepzelca Utilization Review Medical Policy
- Zepzelca™ (lurbinectedin injection – Jazz Pharmaceuticals)

REVIEW DATE: 07/01/2020

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]

Guidelines
The National Comprehensive Cancer Network (NCCN) Small Cell Lung Cancer guidelines 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(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Zepzelca is recommended in those who meet the following criteria:

FDA-Approved Indications

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

   Dosing. Approve the following dosing regimen: Each dose must not exceed 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 injection for intravenous use [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; June 2020.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 9, 2020. Search term: lurbinectedin.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2020 – July 7, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 9, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/01/2020
Update	July 9, 2020: No criteria changes. Updated guidelines in Overview.	NA