Reference number(s)
3970-A

SPECIALTY GUIDELINE MANAGEMENT

ZEPZELCA (lurbinectedin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
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.

B. Compendial Uses
1. Relapsed small cell lung cancer
2. Primary progressive small cell lung cancer

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Small Cell Lung Cancer
Authorization of 12 months may be granted for subsequent treatment of small cell lung cancer as a single agent in any of the following settings:
A. Relapse following complete or partial response or stable disease with initial treatment
B. Primary progressive disease
C. Metastatic disease following disease progression on or after platinum-based chemotherapy

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Zepzelca [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 12, 2023.