Reference number(s)
4726-A

STANDARD MEDICARE PART B 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
3. Ewing sarcoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. 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:
1. Relapse following complete or partial response or stable disease with initial treatment
2. Primary progressive disease
3. Metastatic disease following disease progression on or after platinum-based chemotherapy

B. Ewing Sarcoma
Authorization of 12 months may be granted for subsequent treatment of Ewing sarcoma as a single agent for relapsed, progressive, or metastatic disease.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:

1. No evidence of unacceptable toxicity while on current regimen AND
2. No evidence of disease progression while on current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zepzelca.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Small cell lung cancer
4. NCCN Guideline: Bone cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zepzelca are covered in addition to the following:

1. Relapsed small cell lung cancer
2. Primary progressive small cell lung cancer
3. Ewing sarcoma

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Zepzelca to treat small cell lung cancer and Ewing sarcoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen). Zepzelca is recommended as Subsequent systemic therapy for patients with performance status 0-2 as a single agent for relapse following complete or partial response or stable disease with primary treatment or primary progressive disease.

VI. 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. Available at: https://www.nccn.org. Accessed July 12, 2023.