

CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

Lurbinectedin (Zepzelca[®])

Version: 1.0

EFFECTIVE DATE: 1/1/2024



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Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at <http://www.cms.gov> for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Lurbinectedin (Zepzelca): Discussion

Lurbinectedin is a DNA alkylating agent. It triggers a cascade of events that affect the activity of transcription factors and impairs DNA repair pathways, ultimately leading to double-strand DNA breaks and eventual cell death.¹

Lurbinectedin is an alkylating drug indicated and approved by the FDA for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. This indication is approved under an accelerated approval based on the overall response rate and the duration of response.²

The National Comprehensive Cancer Network (NCCN) endorses lurbinectedin for the treatment of bone cancer and small-cell lung cancer.^{3,4}

Lurbinectedin: Definitions

- **DNA Alkylating Agent** - These prevent cells from dividing and replicating by damaging the DNA.⁵
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN)** - An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Lurbinectedin: Policy

Lurbinectedin will be considered for coverage when the following criteria are met:

Bone Cancer- Ewing Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Second-line therapy as a single agent for one of the following:
 - a) With or without radiation therapy for relapse
 - b) Progressive disease following primary treatment
 - c) Metastatic disease ³

Small Cell Lung Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Subsequent systemic therapy for patients with a performance status of 0-2 as a single agent for one of the following:
 - a) Relapse following complete or partial response or stable disease with primary treatment
 - b) Primary progressive disease ⁴

Note: Coverage of lurbinectedin will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Lurbinectedin: References

1. Lurbinectedin, Mechanism of action. <https://go.drugbank.com/drugs/DB12674>. Accessed August 9, 2023.
2. Lurbinectedin (Zepzelca) Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213702s008lbl.pdf. Accessed August 9, 2023.
3. National Comprehensive Cancer Network Guidelines. Bone Cancer (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed August 9, 2023.
4. National Comprehensive Cancer Network Guidelines. Small Cell Lung Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed August 9, 2023.
5. Alkylating Agents: How Do They Work? <https://www.nursingcenter.com/ncblog/march-2023/alkylating-agents>. Accessed August 9, 2023.

Lurbinectedin: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C34.91	Small Cell Lung Cancer
C41.9	Bone Cancer – Ewing’s Sarcoma
J9223	Lurbinectedin (Zepzelca)

Lurbinectedin: Revision and Review History

NO.	DESCRIPTION	DATE(S)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	8/23/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	9/29/2023
6	Revision Changes:	