Subject:	Zepzelca (lurbinectedin)		
Document #:	ING-CC-0171	**Publish Date:**	~~06/21/2021~~09/19/2022
Status:	Reviewed	**Last Review Date:**	~~05/21/2021~~08/19/2022

Table of Contents

Overview

This document addresses the use of Zepzelca (lurbinectedin). Zepzelca is an alkylating agent used to treat small cell lung cancer (SCLC).

The FDA approved indications for Zepzelca is for the treatment of metastatic small cell lung cancer in individuals with disease progression on or after platinum-based chemotherapy.

Definitions and Measures

Disease Progression: Cancer that continues to grow or spread.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Zepzelca (lurbinectedin)

Requests for Zepzelca (lurbinectedin) may be approved if the following criteria are met:

I. Individual has a diagnosis of advance or metastatic Small Cell Lung Cancer (SCLC) (Label, NCCN 2A); **AND**
   A. Individual is using as single agent for subsequent therapy; **AND**
   B. Individual has confirmation of disease progression on or after platinum-based chemotherapy; **AND**
   C. Individual has a current ECOG performance score of 0-2.

Requests for Zepzelca (lurbinectedin) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9223	Injection, lurbinectedin, 0.1 mg [Zepzelca]

ICD-10 Diagnosis

C34.90-C34.92	Malignant neoplasm of unspecified part of bronchus or lung

Document History

Reviewed: 08/19/2022
Document History:

- 08/19/2022 – Annual Review: No changes. Coding reviewed: No changes.
- 05/21/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 08/21/2020 – Annual Review: Add new clinical criteria document for Zepzelca (lurbinectedin). Coding Reviewed Added HCPCS J3590, J9999, J3490. All diagnosis pend. Effective 1/1/2021 Added HCPCS J9223, Removed J9999, J3590, J3490. Added ICD-10-CM C34.90-C34.92.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 29, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 29, 2022.
    a. Small Cell Lung Cancer. V2.2022. Revised November 24, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.