Medical Policy:

ZEPZELCA™ (lurbinectedin)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.316	January 2, 2024	September 2, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Zepzelca is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

Length of Authorization

Initial authorization will be for no more than 6 months and reauthorization will be for no more than 12 months.

Dosing Limits [Medical Benefit]

Dosing: 3.2 mg/m^2 every 21 days, until disease progression or unacceptable toxicity.

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following condition:

1. **Metastatic small cell lung cancer (SCLC)**
    A. Patient is 18 years of age and older; **AND**
    B. Zepzelca is being prescribed by, or in consultation with an oncologist; **AND**
    C. Patient has disease progression on or after platinum-based chemotherapy.

Limitations/Exclusions

The use of Zepzelca considered experimental or investigational for all other uses

Applicable Procedure Codes

Code	Description
J9223	Injection, lurbinectedin; 1 billable unit = 0.1 mg

Applicable NDCs

Code	Description
68727-0712-xx	Zepzelca 4 mg single dose vial

ICD-10 Diagnoses

Code	Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

Revision History

Company(ies)	DATE	REVISION

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EmblemHealth & ConnectiCare	01/02/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/6/2023	Annual Review: No revisions
EmblemHealth & ConnectiCare	10/13/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	01/01/2021	Updated J-Code
EmblemHealth & ConnectiCare	09/02/2020	New Policy

References

1. Product Information: ZEPZELCA™ intravenous injection, lurbinectedin intravenous injection. Jazz Pharmaceuticals Inc (per FDA), Palo Alto, CA, 2020.

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