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Lurbinectedin

(Zepzelca®) J9223 (0.1 mg)

Covered with prior authorization

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

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

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

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Zepzelca® (lurbinectedin) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:

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This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Zepzelca® is an alkylating agent used to treat small cell lung cancer (SCLC). The FDA approved indication for Zepzelca® is for the treatment of metastatic small cell lung cancer in individuals with disease progression on or after platinum-based chemotherapy. NCCN guidelines state that Zepzelca's® indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. 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.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Small Cell Lung Cancer. V3.2021.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.