Jazz Is Committed to Supporting Access and Reimbursement for ZEPZELCA® (lurbinectedin)

Jazz Pharmaceuticals delivers reimbursement support for offices and helps reduce barriers to access for appropriate ZEPZELCA patients

Access and Reimbursement Managers (ARMs) provide expertise and support

Assistance with reimbursement-related questions about ZEPZELCA

Purchasing, procurement, and distribution support, and education on coding and billing

JazzCares helps appropriate patients get access to ZEPZELCA

Dedicated JazzCares specialists assist patients and practices with:

JazzCares™
Making a difference in Patients' lives, one Patient at a time

- Benefits investigation* to help patients understand their existing insurance coverage for ZEPZELCA
- Prior authorization and appeals information support*
- Financial assistance programs for eligible patients†
- The ZEPZELCA Savings Card—provides eligible commercially insured patients with assistance for out-of-pocket medication costs subject to an annual maximum (restrictions apply)

For more information about JazzCares, visit **www.JazzCares.com**. To speak with a JazzCares specialist or to connect with your ARM—call our team at **1-833-533-JAZZ (5299)**, Monday-Friday, 8 AM - 8 PM ET.

Permanent J-code

Permanent J-code for ZEPZELCA[1]	Description[2]	HCPCS code dosage (billing units)	Example
J9223	Infusion: 3.2 mg/m^2	0.1 mg = 1 unit	4 mg vial = 40 units

*Insurance coverage and plans may vary. The JazzCares Program provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional.
†Subject to financial and residency eligibility criteria.
JW modifier: Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.
HCPCS=Healthcare Common Procedure Coding System.

Please see pages 3-4 for Important Safety Information and click here for full Prescribing Information.

ZEPZELCA® (lurbinectedin) for injection 4 mg

Ordering information

Specialty distributors

ZEPZELCA® (lurbinectedin) is available for purchase from the authorized **Specialty Distributors** listed below. Verify that your facility has an account with their Specialty Distributor before ordering. If not, they should contact their Specialty Distributor. The facility should also contact their Specialty Distributor with questions regarding product returns.

AmerisourceBergen®

ASD Healthcare	Oncology Supply
ASD Healthcare - Phone: (800) 746-6273 Fax: (800) 547-9413 Online: https://www.asdhealthcare.com/home	Oncology Supply - Phone: (800) 633-7555 Fax: (800) 248-8205 Online: https://www.oncologysupply.com

CardinalHealth™

Cardinal Health
Phone: (877) 453-3972 Fax: (877) 274-9897 | Specialty Online (Clinics): https://specialtyonline.cardinalhealth.com Online: Order Express (Hospitals) https://orderexpress.cardinalhealth.com

McKESSON

McKesson Plasma and Biologics (MPB)	McKesson Plasma and Biologics (MPB)
Phone: (877) 625-2566 Fax: (888) 752-7626 Online: https://connect.mckesson.com	Phone: (800) 482-6700 Fax: (800) 289-9285 Online: http://MSCS.McKesson.com

Group purchasing organizations (GPOs)

ZEPZELCA is now available through:

- ION Solutions (AmerisourceBergen®)
- Onmark® GPO (McKesson)
- Unity GPO (The US Oncology Network/McKesson)
- VitalSource™ (Cardinal Health™)

Please see pages 3-4 for Important Safety Information and click here for full Prescribing Information.

INDICATION

ZEPZELCA® (lurbinectedin) is indicated 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 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(s).

IMPORTANT SAFETY INFORMATION

Myelosuppression

ZEPZELCA can cause myelosuppression. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 or 4 neutropenia occurred in 41% of patients, with a median time to onset of 15 days and a median duration of 7 days. Febrile neutropenia occurred in 7% of patients.

Sepsis occurred in 2% of patients and was fatal in 1% (all cases occurred in patients with solid tumors other than SCLC). Grade 3 or 4 thrombocytopenia occurred in 10%, with a median time to onset of 10 days and a median duration of 7 days. Grade 3 or 4 anemia occurred in 17% of patients.

Administer ZEPZELCA only to patients with baseline neutrophil count of at least 1,500 cells/mm^3 and platelet count of at least 100,000/mm^3.

Monitor blood counts including neutrophil count and platelet count prior to each administration. For neutrophil count less than 500 cells/mm^3 or any value less than lower limit of normal, the use of G-CSF is recommended. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

Hepatotoxicity

ZEPZELCA can cause hepatotoxicity. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 elevations of ALT and AST were observed in 6% and 3% of patients, respectively, and Grade 4 elevations of ALT and AST were observed in 0.4% and 0.5% of patients, respectively. The median time to onset of Grade ≥3 elevation in transaminases was 8 days (range: 3 to 49), with a median duration of 7 days.

Monitor liver function tests, prior to initiating ZEPZELCA, periodically during treatment, and as clinically indicated. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

Extravasation Resulting in Tissue Necrosis

Extravasation of ZEPZELCA resulting in skin and soft tissue injury, including necrosis requiring debridement, can occur. Consider use of a central venous catheter to reduce the risk of extravasation, particularly in patients with limited venous access. Monitor patients for signs and symptoms of extravasation during the ZEPZELCA infusion.

If extravasation occurs, immediately discontinue the infusion, remove the infusion catheter, and monitor for signs and symptoms of tissue necrosis. The time to onset of necrosis after extravasation may vary.

Administer supportive care and consult with an appropriate medical specialist as needed for signs and symptoms of extravasation. Administer subsequent infusions at a site that was not affected by extravasation.

Rhabdomyolysis

Rhabdomyolysis has been reported in patients treated with ZEPZELCA.

Monitor creatine phosphokinase (CPK) prior to initiating ZEPZELCA and periodically during treatment as clinically indicated. Withhold or reduce the dose based on severity.

(continued on next page)

IMPORTANT SAFETY INFORMATION (cont'd)

Embryo-Fetal Toxicity

ZEPZELCA® (lurbinectedin) can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 6 months after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 4 months after the final dose.

Lactation

There are no data on the presence of ZEPZELCA in human milk, however, because of the potential for serious adverse reactions from ZEPZELCA in breastfed children, advise women not to breastfeed during treatment with ZEPZELCA and for 2 weeks after the final dose.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions, including laboratory abnormalities, (≥20%) are leukopenia (79%), lymphopenia (79%), fatigue (77%), anemia (74%), neutropenia (71%), increased creatinine (69%), increased alanine aminotransferase (66%), increased glucose (52%), thrombocytopenia (37%), nausea (37%), decreased appetite (33%), musculoskeletal pain (33%), decreased albumin (32%), constipation (31%), dyspnea (31%), decreased sodium (31%), increased aspartate aminotransferase (26%), vomiting (22%), decreased magnesium (22%), cough (20%), and diarrhea (20%).

DRUG INTERACTIONS

Strong and Moderate CYP3A Inhibitors
Avoid coadministration with a strong or a moderate CYP3A inhibitor as this increases lurbinectedin systemic exposure which may increase the incidence and severity of adverse reactions to ZEPZELCA. If coadministration of ZEPZELCA with a moderate CYP3A inhibitor cannot be avoided, consider dose reduction of ZEPZELCA, if clinically indicated.

Strong and Moderate CYP3A Inducers
Avoid coadministration with a strong or moderate CYP3A inducer. Coadministration with a strong CYP3A inducer decreases lurbinectedin systemic exposure which may reduce ZEPZELCA efficacy.

GERIATRIC USE

Of the 105 patients with SCLC administered ZEPZELCA in clinical studies, 37 (35%) patients were 65 years of age and older, while 9 (9%) patients were 75 years of age and older. No overall difference in effectiveness was observed between patients aged 65 and older and younger patients.

There was a higher incidence of serious adverse reactions in patients ≥ 65 years of age than in patients < 65 years of age (49% vs. 26%, respectively). The serious adverse reactions most frequently reported in patients ≥ 65 years of age were related to myelosuppression and consisted of febrile neutropenia (11%), neutropenia (11%), thrombocytopenia (8%), and anemia (8%).

Please click here for full Prescribing Information.
To learn more about ZEPZELCA, please visit www.ZEPZELCAPro.com.

References: 1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-3-2020-drugs-and-biologics.pdf. Accessed April 8, 2022.
2. ZEPZELCA® (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals Pharma Mar

ZEPZELCA® (lurbinectedin) for injection 4 mg