NEW TECHNOLOGY ADD-ON PAYMENT FOR *ZEPZELCA*

New Technology Add-on Payment (NTAP) approved for Medicare inpatient use for ZEPZELCA® (lurbinectedin)[1]

For fiscal year 2022, the maximum NTAP for ZEPZELCA is $8,622.90

NTAPs apply to qualifying cases in the Inpatient Prospective Payment System (IPPS)-participating acute care hospitals. This add-on payment will be incremental to the Medicare Severity Diagnosis Related Group (MS-DRG) reimbursement for qualifying Medicare inpatient cases.

The NTAP payment may help improve access to ZEPZELCA by Medicare beneficiaries in the IPPS hospital setting, and it further underscores how committed Jazz is to making innovative treatments for serious medical conditions widely accessible to appropriate patients.

About NTAP

- Helps facilitate access to new medical services and technologies used to treat Medicare beneficiaries in the IPPS hospital setting
- Provides an incremental reimbursement for new medical services and technologies for Medicare beneficiaries in addition to the standard MS-DRG–based reimbursement to hospitals reimbursed under the IPPS

ZEPZELCA was approved for NTAP by meeting these criteria:

NEW

does not use the same or similar mechanism of action as currently available treatments for metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy

COST

is inadequately paid for under the existing standard MS-DRG system

CLINICAL IMPROVEMENT

fills an unmet need in second-line treatment for extensive-stage SCLC

INDICATION

ZEPZELCA 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).

Please see pages 2-4 for Important Safety Information and click here for full Prescribing Information.

ZEPZELCA® (lurbinectedin) for injection 4 mg

Payment and Timing

CMS limits NTAPs to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS-DRG payment for the case.[1]

Coding information

Hospitals report use of ZEPZELCA® (lurbinectedin) by recording an ICD-10-PCS code on the claim for the traditional Medicare admission, indicating that ZEPZELCA was administered during the admission. These codes are recorded in the same section of the claim as other ICD-10-PCS codes applicable to the admission.[2]

There are 2 specific ICD-10-PCS procedure codes established for appropriate NTAP billing and reimbursement of ZEPZELCA administered to patients in the inpatient hospital setting:

ICD-10-PCS code	Description
XW03387	Introduction of lurbinectedin into **peripheral vein**, percutaneous approach, new technology group 7
XW04387	Introduction of lurbinectedin into **central vein**, percutaneous approach, new technology group 7

For more information, contact your Access and Reimbursement Manager, or call **1-833-533-JAZZ (5299)**, Monday-Friday, 8 AM - 8 PM ET.

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.

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IMPORTANT SAFETY INFORMATION (continued)

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.

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%).

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IMPORTANT SAFETY INFORMATION (continued)

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. 42 CFR Parts 412, 413, 425, 455, and 495. https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf. Accessed April 8, 2022. **2**. Centers for Medicare and Medicaid Services. Health Care Code Sets: ICD-10. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/icd9-10cm-icd10pcs-cpt-hcpcs-code-sets-educational-tool-icn900943.pdf. Accessed April 8, 2022.

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