BlueCross BlueShield Federal Employee Program

ZEPZELCA
(lurbinectedin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zepzelca (lurbinectedin) is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death (1).

Regulatory Status

FDA-approved 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 (1).

Zepzelca can cause myelosuppression. Treatment with Zepzelca should only be initiated if absolute neutrophil count (ANC) is at least 1,500 cells/mm^3 and platelet count is at least 100,000/mm^3. Blood counts should be monitored 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 (1).

Zepzelca can cause hepatotoxicity. Liver function tests should be monitored prior to initiation, periodically during treatment, and as clinically indicated (1).

Zepzelca can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Zepzelca and for 6 months after the final dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Zepzelca and for 4 months after the final dose (1).

The safety and effectiveness of Zepzelca in pediatric patients less than 18 years of age have not been established (1).

Summary

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Zepzelca (lurbinectedin) is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death. The safety and effectiveness of Zepzelca in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zepzelca while maintaining optimal therapeutic outcomes.

References

1. Zepzelca [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2023.
2. NCCN Drugs & Biologics Compendium® Lurbinectedein 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025