Lurbinectedin (ZEPZELCA)
Criteria for Use
August 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *http://vaww.pbm.va.gov* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Lurbinectedin.

- ☐ Immunocompromised patients including known HIV (unless HIV with normal CD-4 counts)
- ☐ Absolute neutrophil count (ANC) < 1500 cells/mm^3 and platelet count <100,000/mm^3
- ☐ Unmanageable strong or moderate CYP3A Inhibitor drug interaction identified (including grapefruit and Seville oranges)
- ☐ Concomitant strong CYP3A inducers
- ☐ Moderate-severe hepatic impairment (T bili > 1.5 times the upper limit of normal and any AST)
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Lactating

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Care is provided by a VA/VA purchased care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Baseline CBC then prior to each administration; baseline LFT's then periodically as indicated

Additional Inclusion Criteria

The answers to the following must be fulfilled in order to meet criteria:

- ☐ Evidence of disease progression on or after platinum-based chemotherapy for metastatic small cell lung cancer (SCLC)
- ☐ Prophylaxis with antiemetic regimen for moderately emetogenic agent
- ☐ Use of granulocyte colony stimulating factor (GCSF) is recommended for ANC < 500 cells/mm^3 as secondary prophylaxis

Additional Inclusion Criteria: Select if applicable

- ☐ Female patients of child-bearing potential: counseling provided on risks vs benefits of treatment and use of effective contraception during therapy and for 6 months after the last dose.
- ☐ Male partners: counseling provided on risks vs benefits of treatment and use of effective contraception during therapy and for 4 months after the last dose.

Prepared: December 2020; Rev Mar 2022; Rev Dec 2023; Rev Aug 2024. Contact: Demetra M. Mylonas, PharmD; Mark C. Geraci, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at *PBM INTERnet* or *PBM INTRAnet*