Lorlatinib (LORBRENA®)
Criteria for Use
May 2021

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 *PBM INTRAnet* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive lorlatinib:

- ☐ Concurrent use of strong CYP3A inducers
- ☐ History of interstitial fibrosis or interstitial lung disease
- ☐ Severe renal impairment (i.e. CrCl < 15 ml/min using Cockroft-Gault or ESRD requiring dialysis)
- ☐ Baseline moderate to severe hepatic impairment [i.e. total bilirubin ≥ 1.5 x ULN with any AST OR AST/ALT > 2.5 x ULN (>5 x ULN in patients with liver metastases)]
- ☐ Inadequate bone marrow function (i.e. ANC < 1,500/mm^3, PLT < 100,000/mm^3, Hgb < 9 g/dL)
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

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

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ ECOG* Performance Status 0-2

Additional Inclusion Criteria

The answer to ONE of the following must be fulfilled to meet criteria:

- ☐ Metastatic non-small cell lung cancer (NSCLC) with a confirmed ALK mutation AND progressive disease or intolerance to at least one prior ALK TKI (e.g. crizotinib, alectinib, brigatinib, ceritinib)
- ☐ Metastatic NSCLC with a confirmed ROS1 rearrangement AND progressive disease or intolerance to entrectinib or crizotinib

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