VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lorbrena® (lorlatinib tablets – Pfizer)

TAC APPROVAL DATE: 11/07/2018

OVERVIEW

Lorbrena, a kinase inhibitor, is indicated for the treatment of patients with anaplastic lymphoma kinase (*ALK*)-positive metastatic non-small cell lung cancer (NSCLC), whose disease has progressed on: Xalkori® (crizotinib capsules) and at least one other ALK inhibitor for metastatic disease; or Alecensa® (alectinib capsules) as the first ALK inhibitor therapy for metastatic disease; or Zykadia® (ceritinib capsules) as the first ALK inhibitor therapy for metastatic disease. This indication is approved under accelerated approval based on tumor 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.

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 1.2019), Xalkori, Zykadia, Alecensa (**preferred**), and Alunbrig™ (brigatinib tablets) are all of the recommended first-line therapies for ALK-positive NSCLC (all category 1).[2] Lorbrena is not addressed in the guidelines. For subsequent therapy with progression on Xalkori, local therapy can be considered, Xalkori can be continued, or therapy can be switched to Zykadia, (if not previously given) Alecensa (if not previously given), or Alunbrig (category 2A). If there is rapid radiographic progression or threatened organ function, continuing Xalkori therapy is not recommended and instead alternate therapies should be considered. The guidelines also refer to NCCN guidelines for CNS Cancers for additional therapies. For progression on Alecensa, Alunbrig, or Zykadia, local therapy should be considered along with continuing Zykadia, Alunbrig, or Alecensa (category 2A). For multiple systemic lesions, initial cytotoxic therapy options for adenocarcinoma or squamous cell carcinoma should be considered (category 2A). Xalkori or Zykadia are recommended as first-line therapy for ROS1 rearrangement-positive NSCLC (both category 2A). Of the two choices, Xalkori is preferred. Xalkori is also recommended as an emerging targeted therapy in patients with high level *MET* amplification or *MET* exon 14 skipping mutation in lung cancer (category 2A).

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Lorbrena. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lorbrena is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** The patient has anaplastic lymphoma kinase (*ALK*)-positive metastatic NSCLC; AND
   - **B)** The patient meets one of the following criteria (i, ii, or iii):
     - **i.** The patient has disease progression on Xalkori (crizotinib capsules) and at least one other ALK inhibitor (e.g., Zykadia [ceritinib capsules], Alecensa [alectinib capsules], Alunbrig [brigatinib tablets]); OR
     - **ii.** The patient has disease progression on Alecensa (alectinib capsules) as the first ALK inhibitor therapy; OR
     - **iii.** The patient has disease progression on Zykadia (ceritinib capsules) as the first ALK inhibitor therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lorbrena has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lorbrena® tablets [prescribing information]. New York, NY: Pfizer Inc.; November 2018.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 1.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 5, 2018.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New Policy	New criteria	11/7/2018

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.