VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lorbrena Prior Authorization Policy
- Lorbrena® (lorlatinib tablets – Pfizer)

REVIEW DATE: 11/18/2020; selected revision 03/17/2021

OVERVIEW

Lorbrena, a kinase inhibitor, is indicated for the treatment of adult patients with **anaplastic lymphoma kinase (*ALK*)-positive metastatic non-small cell lung cancer (NSCLC)** as detected by an FDA-approved test.[1]

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 4.2021 – March 3, 2021), Alecensa® (alectinib capsules), Alunbrig™ (brigatinib tablets), and Lorbrena are all category 1, first-line,preferred regimens.[2] Other category 1 recommended regimen is Zykadia® (ceritinib capsules). Xalkori is listed as useful in certain circumstances, but it's also a category 1 option. Lorbrena is also recommended as subsequent therapy upon progression on Alecensa, Alunbrig, or Zykadia (category 2A). If Xalkori is used first-line, then Lorbrena is used for subsequent therapy after progression on Alecensa, Alunbrig, or Zykadia (category 2A). Lorbrena is also recommended as subsequent therapy after progression on Xalkori, Rozlytrek (entrectinib capsules) [both "Preferred"], or Zykadia [all category 2A] for ROS1 rearrangement-positive NSCLC. Zykadia is listed as "other recommended" agent in the first-line setting for ROS1 rearrangement.

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)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*)-positive metastatic NSCLC, as detected by an approved test.

Other uses With Supportive Evidence

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has *ROS1* rearrangement-positive disease; AND
   C) Patient has tried at least one of Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), or Rozlytrek (entrectinib capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lorbrena is not recommended in the following situations:

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; March 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2021 – March 3, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 16, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/7/2018
Annual Revision	Added new approval condition for ROS1-positive non-small cell lung cancer.	11/13/2019
Annual Revision	**Non-Small Cell Lung Cancer:** Added new criteria for use of Lorbrena after first-line Alunbrig, based on guidelines. Deleted "as the first anaplastic lymphoma kinase (ALK) inhibitor therapy" after Alecensa and Zykadia criteria, since it's not needed.	11/18/2020
Selected Revision	**Non-Small Cell Lung Cancer:** Based on FDA-approval in the first-line setting, deleted criteria requiring prior use of another ALK inhibitor therapy. Added age requirement criterion and added "as detected by an approved test" in reference to ALK mutation testing, as per the label. **Non-Small Cell Lung Cancer:** Under "Other uses with supportive evidence", moved "ROS1 Rearrangement Positive" descriptor from indication to within criteria. Added age criterion to match FDA-approved use above. Reworded criterion referring to patient has "disease progression on" to "Patient has tried at least one of". Added Rozlytrek (entrectinib capsules) as another agent patient could have tried.	03/17/2021