PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/30/2022; selected revision 01/11/2023

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

GUIDELINES
Lorbrena is addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2-5]
- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) recommend Lorbrena as a "useful in certain circumstances" treatment option for *ALK*-positive Erdheim-Chester disease (category 2A).[3]
- **NSCLC:** Guidelines (version 1.2023 – December 22, 2022) recommend testing for biomarkers (e.g., *ALK* rearrangement, *ROS* proto-oncogene 1 (*ROS1)* gene rearrangement) in eligible patients with NSCLC.[4]
  - *ALK*-rearrangement-positive NSCLC: If *ALK* rearrangement is discovered prior to first-line systemic therapy, Lorbrena is a preferred first-line treatment option (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, options are to complete the planned systemic therapy (including maintenance therapy) or to interrupt the systemic therapy and treat with Lorbrena (preferred, category 2A) or another ALK inhibitor. Lorbrena is also recommended for patients who progress on other *ALK* inhibitors (category 2A).
  - *ROS* proto-oncogene 1 *(ROS1)* rearrangement-positive NSCLC: Lorbrena is a recommended subsequent therapy (category 2A) for patients who progress on Zykadia® (ceritinib capsules and tablets), Xalkori® (crizotinib capsules), or Rozlytrek™ (entrectinib capsules). Lorbrena is not a recommended first-line treatment option for *ROS1* rearrangement-positive NSCLC.
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2022 – May 17, 2022) and NCCN Uterine Neoplasms guidelines (version 1.2023 – December 22, 2022) recommend Lorbrena as a treatment option for IMT with *ALK* translocation.[5,6]

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 one of the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (*ALK*)-Positive.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   - **D)** The mutation was detected by an approved test.

Other uses With Supportive Evidence

2. **Erdheim-Chester Disease**. Approve for 1 year 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*) rearrangement/fusion-positive disease.

3. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patients meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND.
   - **C)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient has advanced, recurrent, or metastatic disease; OR
     - **ii.** The tumor is inoperable.

4. **Non-Small Cell Lung Cancer – *ROS1* Rearrangement-Positive.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has *ROS1* rearrangement-positive disease; AND
   - **D)** Patient has tried at least one of Xalkori (crizotinib capsules), Zykadia (ceritinib capsules or tablets), 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 Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2022. Search term: lorlatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2022.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023 - December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2022.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022) © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.