Reference number(s)
2787-A

SPECIALTY GUIDELINE MANAGEMENT

LORBRENA (lorlatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Lorbrena is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

B. Compendial Uses
1. Single-agent therapy for recurrent, advanced or metastatic NSCLC in patients with:
   a. ALK rearrangement-positive tumors
   b. ROS1 rearrangement-positive tumors, following disease progression on crizotinib, entrectinib or ceritinib
2. Inflammatory myofibroblastic tumor (IMT) with ALK translocation

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart documentation indicating ALK mutation status or ROS1 rearrangement status (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer (NSCLC)
1. Authorization of 12 months may be granted for treatment of ALK rearrangement-positive recurrent, advanced or metastatic NSCLC as a single-agent.

2. Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic NSCLC as a single-agent therapy when all of the following criteria are met:
   a. The disease is ROS1 rearrangement-positive
   b. The disease has progressed on any of the following: ceritinib, crizotinib, or entrectinib.

B. Inflammatory Myofibroblastic Tumor (IMT)
Authorization of 12 months may be granted for treatment of ALK-positive IMT as a single agent.

IV. CONTINUATION OF THERAPY

A. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for continued treatment of non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

B. Inflammatory Myofibroblastic Tumor (IMT)

Authorization of 12 months may be granted for continued treatment of inflammatory myofibroblastic tumor in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Lorbrena [package insert]. New York, NY: Pfizer, Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 5, 2022.