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 Indication
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
3. Erdheim-Chester disease with ALK fusion

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 advanced or metastatic NSCLC (including brain metastases from NSCLC) as a single-agent.

2. Authorization of 12 months may be granted for treatment of 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.

C. Erdheim-Chester Disease
Authorization of 12 months may be granted for treatment of ALK-positive Erdheim-Chester disease 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) and Erdheim-Chester Disease
Authorization of 12 months may be granted for continued treatment of inflammatory myofibroblastic tumor or Erdheim-Chester disease 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 July 14, 2022.