

Commercial/Healthcare Exchange PA Criteria

Effective: February 6th, 2019

Prior Authorization: Lorbrena

Products Affected: Lorbrena (lorlatinib) oral tablets

Medication Description: Lorbrena 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 crizotinib and at least 1 other ALK inhibitor for metastatic disease, alectinib as the first ALK inhibitor for metastatic disease, or ceritinib as the first ALK inhibitor 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.

Covered Uses: Anaplastic lymphoma kinase positive metastatic non-small cell lung cancer, progressed on alectinib or ceritinib as first ALK inhibitor therapy or crizotinib and a least 1 other ALK inhibitor for metastatic disease

Exclusion Criteria: Concomitant treatment with strong CYP3A inducers.

Required Medical Information:

1. Confirmed ALK-positive NSCLC as detected by an FDA-approved test
2. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration:

Initial: 12 months

Continuation: 3 years

Other Criteria:

- A. Patient has a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer as detected by an FDA-approved test; AND
- B. Patient has had disease progression on Xalkori (crizotinib) and at least one other ALK inhibitor for metastatic disease; OR
- C. Patient has had disease progression on Alecensa (alectinib) as the first ALK inhibitor therapy for metastatic disease; OR
- D. Patient has had disease progression on Zykadia (ceritinib) as the first ALK inhibitor therapy for metastatic disease.

References:

1. Lorbrena[®] tablets [prescribing information]. New York, NY: Pfizer Inc.; November 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/02/2019
2	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019

Last Res. July 1st, 2019