

## Commercial/Healthcare Exchange PA Criteria

Effective: February 6<sup>th</sup>, 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<sup>®</sup> tablets [prescribing information]. New York, NY: Pfizer Inc.; November 2018.

## Policy Revision history

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
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