UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lorbrena

Program	Prior Authorization
Medication	Lorbrena® (lorlatinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2018
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Lorbrena (lorlatinib) is a kinase inhibitor 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 one other ALK inhibitor for metastatic disease; or
- alectinib as the first ALK inhibitor therapy for metastatic disease; or
- ceritinib as the first ALK inhibitor therapy 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.[1]

In addition, the National Cancer Comprehensive Network (NCCN) also recommends Lorbrena for the treatment of NSCLC as single-agent therapy in patients with ALK-positive recurrent, advanced, or metastatic disease following disease progression on first line crizotinib and subsequent therapy with crizotinib for asymptomatic disease and isolated lesions, as well as ALK-positive recurrent, advanced, or metastatic disease following disease progression on first line therapy with brigatinib. NCCN also recommends Lorbrena for the treatment of NSCLC as single agent therapy in patients with ROS1 rearrangement positive tumors as subsequent therapy following disease progression on crizotinib, entrectinib, or ceritinib.

2. Coverage Criteria:

A. <u>Non-small cell lung cancer (NSCLC)</u>

1. <u>Initial Authorization</u>

a. **Lorbrena** will be approved based on **all** of the following criteria:

(1) Diagnosis of NSCLC

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. Disease is both of the following:

- Advanced, metastatic, or recurrent
- Anaplastic lymphoma kinase (ALK)-positive

-AND-

ii. Disease has progressed on at least one of the following therapies:

- Xalkori (crizotinib)
- Alecensa (alectinib)
- Zykadia (certinib)
- Alunbrig (brigatinib)

-OR-

(b) **Both** of the following:

i. Disease is both of the following:

- Advanced, metastatic, or recurrent
- ROS proto-oncogene 1 (ROS1)-positive

-AND-

ii. Disease has progressed on at least one of the following therapies:

- Xalkori (crizotinib)
- Rozlytrek (entrectinib)
- Zykadia (ceritinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. Lorbrena will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lorbrena therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Lorbrena** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lorbrena** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Lorbrena therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lorbrena [package insert]. New York, NY: Pfizer Labs, May 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 29, 2020.

Program	Prior Authorization
Change Control	
Date	Change
12/2018	New program
12/2019	Updated criteria for ROS1 positive tumors per NCCN. Updated background and references.
12/2020	Annual review. Updated background and criteria to reflect NCCN guidance. Updated references.