UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1267-5
Program	Prior Authorization/Notification
Medication	Lorbrena® (lorlatinib)
P&T Approval Date	12/2018, 12/2019, 12/2020, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

1. **Background:**
Lorbrena (lorlatinib) is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

In addition, the National Cancer Comprehensive Network (NCCN) recommends Lorbrena for the treatment of NSCLC as single-agent therapy in patients with ALK-positive recurrent, advanced, or metastatic disease as preferred first-line therapy, for patients intolerant to crizotinib, following disease progression on first line therapy with lorlatinib as continuation of therapy except in cases of symptomatic systemic disease with multiple lesions, for ALK G120R as subsequent therapy following disease progression on first -line therapy with either alectinib, brigatinib, or ceritinib, as subsequent therapy following disease progression on first-line therapy with crizotinib, and as subsequent therapy for further progression following disease progression on first-line therapy with either alectinib, brigatinib or ceritinib and subsequent therapy with continuation of either alectinib, brigatinib or ceritinib except in cases of symptomatic systemic disease with multiple lesions..

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.

NCCN also recommends Lorbrena as single-agent treatment for limited and extensive brain metastases in patients with ALK rearrangement-positive NSCLC.

The use of Lorbrena is also recommended by the NCCN as first-line or subsequent therapy for ALK-fusion target as a single agent for Erdheim-Chester Disease (ECD) with symptomatic disease or relapsed/refractory disease and as preferred single-agent therapy for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Non-small cell lung cancer (NSCLC)

1. **Initial Authorization**

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

      (1) Diagnosis of NSCLC

      -AND-

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

         (a) Disease is **both** of the following:

            i. Recurrent, advanced, or metastatic
            ii. Anaplastic lymphoma kinase (ALK)-positive

            -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:

               - Rozlytrek (entrectinib)
               - Xalkori (crizotinib)
               - 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.

C. Histiocytic Neoplasms

1. Initial Authorization

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

(1) Diagnosis of Erdheim-Chester Disease (ECD)

-AND-

(2) Disease is **both** of the following:

(a) Symptomatic, relapsed, or refractory

-AND-

(b) ALK-positive

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.

D. Soft Tissue Sarcoma

1. Initial Authorization

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

(1) Diagnosis of inflammatory myofibroblastic tumor (IMT)

-AND-

(2) Disease is ALK-positive

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.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; March 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed December 19, 2022.

Program	Prior Authorization/Notification – Lorbrena (lorlatinib)
Change Control	
12/2018	New program.
12/2019	Updated criteria according to NCCN guidelines. Added general NCCN recommendations for use criteria. Updated background and references.
12/2020	Annual review. Updated background and criteria to reflect NCCN guidance. Updated references.
2/2022	Annual review. Updated background and criteria to reflect updated NSCLC indication and NCCN guidelines. Updated references.
2/2023	Annual review. Updated background and coverage criteria to reflect updated NCCN guidelines. Added state mandate footnote and updated NCCN reference.