UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1267-7
Program	Prior Authorization/Notification
Medication	Lorbrena® (lorlatinib)
P&T Approval Date	12/2018, 12/2019, 12/2020, 2/2022, 2/2023, 2/2024, 2/2024
Effective Date	5/1/2025

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 patients with ALK-positive recurrent and advanced NSCLC and in patients with ROS1 rearrangement positive recurrent, advanced, or metastatic NSCLC.

The use of Lorbrena is also recommended by the NCCN for the treatment of Erdheim-Chester Disease (ECD) with symptomatic or relapsed/refractory disease, treatment of advanced, recurrent/metastatic, or inoperable uterine sarcoma, treatment of limited and extensive brain metastases in patients with ALK rearrangement-positive NSCLC, treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation, and treatment of relapsed or refractory ALK-positive peripheral T-Cell and large B-Cell lymphoma.

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. <u>Patients less than 19 years of age</u>

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

1. **<u>Initial Authorization</u>**

   a. **Lorbrena** will be approved based on **<u>all</u>** 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:

- Augtyro (repotrectinib)
- 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. Uterine Sarcoma

1. **Initial Authorization**

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

(1) Diagnosis of uterine sarcoma

-AND-

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

(a) Advanced
(b) Recurrent/metastatic
(c) Inoperable

-AND-

(3) 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.

F. Lymphoma

1. **Initial Authorization**

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

(1) **One** of the following diagnoses:

(a) Anaplastic large cell lymphoma (ALCL)

-OR-

(b) Large B-Cell lymphoma

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) 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.

G. 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; April 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed December 20, 2024.

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.
2/2024	Annual review. Added criteria for NCCN recommended use of Lorbrena in uterine sarcoma, peripheral T-Cell lymphoma and large B-cell lymphoma. Updated background and references.

2/2025	Annual review. Added Augtyro (repotrectinib) as a first-line therapy option for ROS1 positive NSCLC per NCCN. Updated references.