UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3158-4
Program	Step Therapy
Medication	Lorbrena® (lorlatinib)
P&T Approval Date	7/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. **Background:**
Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two kinase inhibitors before providing coverage for Lorbrena (lorlatinib) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

Alecensa® (alectinib), Alunbrig® (brigatinib), and Lorbrena are kinase inhibitors indicated for the treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test. The National Comprehensive Cancer Network (NCCN) also supports use of Alecensa, Alunbrig and Lorbrena for treatment of ALK-positive metastatic NSCLC.

Members currently on Lorbrena therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b]:

A. Patients less than 19 years of age

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

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. ALK-Positive Metastatic Non-Small Cell Lung Cancer

1. **Lorbrena** will be approved based on **both** of the following criteria:

   a. Diagnosis of ALK-positive metastatic non-small cell lung cancer

   -AND-

   b. **One** of the following:

      (1) Provider attests the patient has a contraindication, history of intolerance, or that the patient is not an appropriate candidate (document reason) to **both** of the following therapies:

         (a) Alecensa (alectinib)

         (b) Alunbrig (brigatinib)

      -OR-

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

         (a) Patient is currently on Lorbrena therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Pfizer Oncology Together™ program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Lorbrena

   Authorization will be issued for 12 months.

C. Other Indications

1. **Lorbrena** will be approved

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.
[b] Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.

4. References:

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; September 2021.
2. Alunbrig [package insert]. Cambridge, MA: Ariad Pharmaceuticals, Inc; February 2022.
3. Lorbrena [package insert]. New York, NY: Pfizer Labs; April 2023.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 26, 2024.

Program	Step Therapy - Lorbrena (lorlatinib)
Change Control	
7/2021	New program.
4/2022	Annual review with no change to clinical coverage criteria. Updated oncology medications state mandate note. Updated references.
4/2023	Annual review with no change to clinical coverage criteria. Updated background and references.
4/2024	Annual review with no change to coverage criteria. Updated references.