BlueCross BlueShield Arizona

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| **PHARMACY COVERAGE GUIDELINES** | |
| **SECTION: DRUGS** | |
| **ORIGINAL EFFECTIVE DATE:** | **2/21/2019** |
| **LAST REVIEW DATE:** | **2/17/2022** |
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# LORBRENA® (lorlatinib) oral tablet

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

# LORBRENA® (lorlatinib) oral tablet

**Criteria**:

- **Criteria for initial therapy:** Lorbrena (lorlatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)

     b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Documentation of ALK-positivity in tumor specimens
     b. Serum cholesterol and triglycerides
     c. Electrocardiogram
     d. Fasting serum glucose
     e. Negative pregnancy test in a woman of childbearing potential
     f. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2

  5. There are **NO** contraindications
     a. Contraindications include:
        i. Concurrent use with strong CYP3A inducers

  6. Individual does not have end-stage renal disease requiring dialysis (CrCl < 15 mL/min)

  7. Individual does not have moderate to severe hepatic impairment

  8. There are no significant interacting drugs

  **Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Lorbrena (lorlatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

# LORBRENA® (lorlatinib) oral tablet

2. Individual's condition has responded while on therapy
    a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Requested dose is at least 50 mg once daily

4. Individual has been adherent with the medication

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Life-threatening central nervous system effects
        ii. Recurrent complete AV block
        iii. Interstitial Lung Disease/pneumonitis of any severity
        iv. Severe or recurrent life-threatening hypertension not adequately controlled with medical management and dose modification
        v. Severe or life-threatening hyperglycemia not adequately controlled with medical management and dose modification
        vi. Severe hepatotoxicity

6. Individual does not have end-stage renal disease requiring dialysis (CrCl < 15 mL/min)

7. Individual does not have moderate to severe hepatic impairment

8. There are no significant interacting drugs

**Renewal duration**: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-cancer Medications**

    2. **Off-Label Use of Cancer Medications**

**Description:**

Lorbrena (lorlatinib) is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

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Lorlatinib is a kinase inhibitor with in vitro activity against ALK and ROS1 as well as TYK1, FER, FPS, TRKA, TRKB, TRKC, FAK, FAK2, and ACK. Lorlatinib demonstrated in vitro activity against multiple mutant forms of the ALK enzyme, including some mutations detected in tumors at the time of disease progression on crizotinib and other ALK inhibitors.

Non-small cell lung cancer (NSCLC) accounts for about 85% of lung cancer cases. It is estimated that 75% of NSCLC patients are diagnosed late in the course of their disease and already have metastatic or advanced disease. As a result, the five-year survival rate is only 5%. Epidemiology studies suggest that approximately 3-5% of NSCLC tumors are ALK-positive.

**Resources:**

Lorbrena (lorlatinib) product information, revised by Pfizer Laboratories Div Pfizer, Inc. 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 03, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 7.2021 – Updated October 29, 2021. Available at https://www.nccn.org. Accessed November 29, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.