



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/18/2021  
LAST REVIEW DATE:  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## EXKIVITY™ (mobocertinib)

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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.

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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### Criteria:

- **Criteria for initial therapy:** Exkivity (mobocertinib) 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. Locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations
    - 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. Left ventricular ejection fraction
    - b. QTc is less than or equal to 470 msec in a woman and less than or equal to 450 msec in a man
    - c. Negative pregnancy test in a woman of childbearing potential
    - d. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1
  5. Individual does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m<sup>2</sup>)
  6. Individual does not have severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase
  7. There are no significant interacting drugs

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Exkivity (mobocertinib) 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
  2. Individual's condition has responded/worsened while on therapy
    - a. Response is defined as:
      - i. No evidence of disease progression
      - ii. Documented evidence of efficacy, disease stability and/or improvement



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3. Individual has been adherent with the medication
4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
  - a. Significant adverse effect such as:
    - i. Interstitial lung disease
    - ii. Pneumonitis
    - iii. QTc prolongation
    - iv. Torsades de pointes
    - v. Polymorphic ventricular tachycardia
    - vi. Heart failure
    - vii. Reduced ejection fraction
    - viii. Diarrhea
    - ix. Other life-threatening adverse reaction that does not recovery within 2 weeks of discontinuation or if it recurs
5. Individual does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m<sup>2</sup>)
6. Individual does not have severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any aspartate aminotransferase
7. 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 a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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### **Description:**

Exkivity (mobocertinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).



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### Resources:

Exkivity (mobocertinib) product information, revised by Takeda Pharmaceuticals America, Inc. 09-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed October 05, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 6.2021 – Updated September 30, 2021. Available at <https://www.nccn.org>. Accessed October 05, 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.

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