UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1371-3
Program	Prior Authorization/Notification
Medication	Exkivity™ (mobocertinib)
P&T Approval Date	11/2021, 11/2022, 11/2023
Effective Date	2/1/2024

1. Background:

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, whose disease has progressed on or after platinum-based chemotherapy.

Indications approved under accelerated approval are based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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. **Exkivity** 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. **Exkivity** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of non-small cell lung cancer (NSCLC)

      -AND-

      (2) Disease is locally advanced or metastatic

-AND-

(3) Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

-AND-

(4) Used as subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Exkivity** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Exkivity therapy

Authorization will be issued for 12 months.

C. 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. Exkivity [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 4, 2023

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Change Control	
11/2021	New program.
11/2022	Annual review. Added stated mandate.
11/2023	Annual review with no change to clinical criteria. Updated background and reference.